Protection of Traditional Chinese Medicine

Part III Clinical Trial Data

Class: Second class protection (extended protection period)

Name of drug: Pule'an Tablet (Conprosta)

Name of Data Item: Clinical Trial Data Item No.: 17

Applying Unit: Zhejiang Conba Pharmaceutical Co., Ltd.

Summary Report on Clinical Trial of Qianliekang®

Pule'an Tablet (Conprosta) in Prostatics Treatment

Unit in Charge of the Clinical Research:

Beijing Hospital

Units Participating in the Clinical Research:

China-Japan Friendship Hospital

General Hospital of the People's Liberation Army (301 Hospital)

The First Affiliated Hospital of Zhejiang Chinese Medical University

Guangxing Hospital Affiliated to Zhejiang Chinese Medical University

Sir Run Run Shaw Hospital Affiliated to School of Medicine of Zhejiang University

Unit in Charge of Statistics:

Medical Statistics Teaching and Research Section of China PLA Postgraduate Medical School (General Hospital of PLA)

Applying Unit: Zhejiang Conba Pharmaceutical Co., Ltd.

June, 2007

Summary Report on Clinical Trial of Qianliekang® Pule'an Tablet in Prostatics Treatment

In order to apply for protection (continued) of TCM product Qianliekang® Pule'an Tablet according to the file Zhe Zhong Bao Lin (2005) No.5 issued by Zhejiang Food and Drug Administration, Pharmacology Clinical Trial Base at Beijing Hospital of Ministry of Health, which was entrusted to be in charge of the clinical research of the medicine, together with the participating hospitals, including China-Japan Friendship Hospital, The General Hospital of General Hospital of PLA (301 Hospital), The First Affiliated Hospital of Zhejiang Chinese Medical University (hereinafter referred to as First Affiliated Hospital of ZCMU), Guangxing Hospital Affiliated to Zhejiang Chinese Medical University (hereinafter referred to as Guangxing Hospital) and Sir Run Run Shaw Hospital, Affiliated to School of Medicine of Zhejiang University (hereinafter referred to as Sir Run Run Shaw Hospital), made clinical observation and trial on Qianliekang® Pule'an Tablet produced by Zhejiang Conba Pharmaceutical Co., Ltd. for a period from Sept. 2006 to June 2007. Cernilton was used as comparative medicine for prostatitis indication in the clinical observation. As the member of cases of Sir Run Run Shaw Hospital fell short of standard and the case grouping violated principle of random, the observation result of the hospital is not listed in curative effect statistics. The summary of the result is as below:

I. Trial Purpose

Main purpose: to evaluate clinical efficacy of Pule'an tablet in chronic prostatitis treatment by pre-treatment observation of the change in NIH-CPSI score, the main symptoms and the physical sign scores. Minor purpose: to observe the change in number of white blood cells and small partials of lecithin through EPS microscopical examination; ultrasound diagnosis of prostate and change of residual urine volume

Observe the function of the heart, liver and kidney as well as the possible adverse accidents to evaluate the safety of the tablet.

II. Design of Trial and Grouping Method

1. Trial Design Types: Random, open and parallel comparison design, non-inferiority test.

2. Trial Design Principle

(1) Cases Load: 220 cases, 165 cases for trial group; 55 cases for control group

(2) Grouping method: Central stratified randomization and blocking randomization with proportion of 3: 1. SAS statistics analysis system was used in random arrangement of the 220 cases in treatment (investigational new drug and control drug), that is, list 001~220 corresponding treatment allocation (attached with randomization project). This trial is jointly finished by 6 hospitals.

(3) Control drug: Prostat Tablet (trade name: Cernilton). Reason: Prostate Tablet has indication similar to that of Pule'an tablet and is a comparative drug with recognized curative efficacy in China. Thus it meets the requirement of comparable product with well-recognized efficacy

III. General Information

176 outpatient and inpatient male patients with prostatitis, aged between 18-50, were selected as observation objects, of which 135 cases were for trial group, 41 were for control group.

In trial group, the average age was 35.73 ranging from oldest age of 44.78 to youngest age of 19.03 with median age of 34.66; duration of symptom was 23.87 in average ranging from minimum 2 months to maximum 23.87 months with median 14 months.

In control group: the average age was 35.73 ranging from oldest age of 49.36 to youngest age of 21.96 with median age of 32.56; duration of symptom was 24.29 months ranging from minimum 3 months to maximum 120 months with median of 13 months.

IV. Standards for Case Selection

(I) Diagnosis Standard

Guiding Principle for Clinical Study in Treatment of Chronic Prostatitis (non-specific) With New Chinese Medicine (refer to state-compiled textbooks for national higher institutions of Chinese medicine), Chinese Traditional Surgery (6^{th} version) and Urology edited by Wu Jieping.

1. There are two types of symptom. The first one is irritation symptom of lower urinary tract, and the second one is inflammatory response or reflex pain symptom. The symptom is shown as frequent urination, urgent urination, odynuria, endless urination, calor mordax of urethra; a little white secretion gets out when getting up in the morning, at the end of urination or defecation. Perineum, genitalia area, lower abdomen, upper area of pubis, lumbosacral area and area around anus feel falling swell and ache.

2. Palpation of prostate. Texture: plump gland, or uneven hardness, or with inflammatory nodules,

or pliable texture. Tenderness: limited tenderness. Size: it can become larger, normal or smaller.

3. Microscopic examination of expressed prostatic secretion (EPS) shows that WBC≥10 /HP; Lecithin corpuscles decrease or disappear.

4. Examination of semen. When expressed prostatic secretion (EPS) can be obtained, please obtain semen for an examination. It is subject to Wright-Giemsa Stain microscopic examination, and WBC＞1×10 6/ml is abnormal.

5. Bacterial culture of expressed prostatic secretion (EPS). If its bacterial culture is rigid, has urinary tract infection history and repeated bacterial culture shows the same pathogenic bacteria, it shall be diagnosed to be bacterial prostatitis. If its bacterial culture is negative, it shall be diagnosed to be nonbacterial prostatitis.

6. Pre and post massage test (PPMT): If only the first cup of urine is turbid, it is preurethritis; if both cups of urine are turbid, it is posterior urethritis. Compare EPS or VB3 with VB1, if there is at least one pair of differences, it shall be diagnosed to be prostatitis. When bacteria number of VB1 is more than that of VB3, it shall be considered infection of anterior urethra. When bacteria number of VB1 is less than that of VB3, it shall be diagnosed according to results of EPS.

7. Ultrasonic examination

Obvious abnormality of ultrasonogram: the size of prostate is normal or smaller; internal echo is uneven; there is enhanced facula and nodule echo; the sound of capsule is enhanced, thickened and coarse.

Mild abnormality of ultrasonogram: the size of prostate is normal or bigger; internal echo is a little stronger or weaker; the echo of capsule is not clear enough.

If the patient has one of (1) (2) (3) symptom, confirmed diagnosis can be made. (4)~(7) item are optional if necessary.

(II) Inclusion Criteria

1. Those who reach the diagnosis standard of chronic prostatitis;

2. Sign “Information Consent Form”;

3. 18~50 years old;

4. The course of disease is over 3 months.

(III) Exclusion criteria

1. Those who don’t reach the diagnosis standard of chronic prostatitis;

2. Below 18 years old or above 51 years old;

3. The course of disease is within 3 months;

4. Patients with acute prostatitis;

5. As for patients with local pains, pay attention to eliminate the possibility of other diseases in lower abdomen, perineum, lumbosacral area and so on, such as ureteral calculus, vesical calculus, inguinal hernia, puic ostitis, varicocele, epididymitis, diseases of the colon and rectum, waist and back myofascitis and so on;

6. Those who have severe primary diseases in heart, brain, liver and hematopoietic system; those who have allergic constitution or who are allergic to many medicines;

7. Subjects who are participating in other clinical trials;

8. Those who don't cooperate during treatment;

9. Those who have drug allergy history;

10. Those who have pollen allergy;

11. Venereal disease (urinary tract infection, urethritis)

12. Other patients who are not suitable to participate in clinical trials in investigators' opinion;

(IV) Drop out case and standard of reject

1. Conditions for subjects to quit or cease the trial

(1) In case of allergic reaction or serious adverse events, the doctor should determine to stop the clinical trial subject, and this case of clinical trial shall be ceased.

(2) In case of deterioration during the course of disease, the doctor determines to stop the clinical trial subject, and this case of clinical trial shall be ceased. This case shall be regarded to be ineffective case.

(3) If the patient is unwilling to continue this clinical trial during the process, and make a request to the responsible doctor to quit the clinical trial, this case can be stopped.

2. Conditions for premature termination of the trial

(1) Serious adverse events occur during the trial;

(2) During the trial, the curative effect of experimental drug is found to be too bad, and has no clinical value.

(3) Major deviations occur in the design or implementation of clinical trial projects, so it is difficult to evaluate drug effects.

(4) Due to lack of fund or other reasons, the sponsor wants to terminate the clinical trial in advance.

In case of premature termination of the trial, all study parties shall be notified in time.

3. Drop out and disposal of cases

(1) Standard of drop out: due to some reasons, those subjects, who give informed consent and are qualified to participate the random trial, don't finish course of treatment and observation period stated in this project. In this case, they shall be regarded as drop out cases. However, this doesn't include subjects who are cured and stop the treatment in advance.

(2) Disposal of drop out cases

① After the subject is drop out, investigators shall try their best to contact the subject by paying a visit, follow-up with a reservation, telephone or mails and other ways, inquire reasons, record the time of the last dosage, and finish evaluation projects as much as possible.

② If the subject quits due to allergy, other adverse reactions and ineffective treatment, investigators shall take corresponding therapeutic measures depending on the subject's actual conditions.

③ Relevant test data of drop out cases shall be kept properly in archives, and get ready for analysis and statistics. Drop out cases don't need substitutes.

(V) Reject of cases

1. "Violation of validity" means that case selection violates inclusion standard, and shall not be included in randomization.

2. The subject hasn't used the experimental drug.

3. There is no data after randomization.

Before data statistics and analysis, statisticians and main investigators discuss and judge whether the case shall be rejected or not.

V. Experimental Drug and Therapeutic Scheme

1. Experimental drug and name

(1) Experimental drug: Qianliekang Brand Pule'an Tablet provided by the sponsor. Specification: 60 tablets/bottle.

(2) Control drug: Prostat Tablet, produced by Nanjing MeiRui Pharma Co., Ltd. Specification: 20 tablets/bottle.

2. Package of experimental drug

Because this is open experiment, there are no special requirements on the package of

experimental drugs.

3. Codes of experimental drug. The sponsor adds consecutive serial numbers to experimental drug. Code of experimental drug is the only identification code of the subjects.

4. Distribution of experimental drug

Experimental drugs shall be distributed according to the coding of experimental center and serial numbers of experimental drug, as well as the number of cases.

Every research unit shall designate one controller of experimental drug. Investigators choose qualified subjects. After the subject signs “Information Consent Form” and investigators write the case history, the controller of experimental drug will distribute drugs according to the treatment sequence of subjects and codes of experimental drugs (otherwise, randomization will be destroyed), and then register in “Use Record of Clinical Trial Medicines”.

5. Stocktaking of experimental drugs

During every follow-up visit, investigators shall record the distribution amount of experimental drugs, subjects’ intake amount and return amount.

Standard of subjects’ intake compliance=(actual intake amount/ prescriptive intake amount) × 100%. If compliance is 80%~120%, the compliance is good.

6. Dosing

Trial group: Pule’an Tablet, oral administration, 4 tablets every time, 3 times per day

Control group: Prostat Tablet, oral administration, 1 tablet every time, 2 times per day

Time of observation is 8 weeks. At the end of the 4^{th} week, give symptom scores and don’t carry out laboratorial examination. At the end of the 8^{th} week, give symptom scores and carry out laboratorial examination.

VI. Observation Items

(I) General records

Codes of experimental drugs, codes of hospitals, initials of subjects, outpatient/inpatient, date of starting the experiment

(II) Observation indicator

1. Biological indicators

Demographic characteristics: gender, age, height, weight

Vital signs: body temperature, resting heart rate, breath, blood pressure after 10-minute rest

(systolic pressure and diastolic pressure) and so on

2. Diagnostic indicators

Symptoms and signs, course of disease, severity extent

Diagnostic indicators of physico-chemical examination: B-ultrasonic examination, WBC number of expressed prostatic secretion (EPS).

3. Indicator for curative effect

(1) Clinical symptoms, signs and NIH-CPSI score of chronic prostatitis (the score table is as follows)

The National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI)

I. Pain and discomfort

1. In the past 1 week, do you have pain or discomfort in following part?

a. Between recta (anus) and testicle (scrotum), that is, private parts

Yes ( ) 1 No ( ) 0

b. Testicle

Yes ( ) 1 No ( ) 0

c. The head of penis (without pertinence to emiction)

Yes ( ) 1 No ( ) 0

d. below the waist, bladder or pubis

Yes ( ) 1 No ( ) 0

2. Have you experienced following events in the past 1 week?

a. The urethra burns or aches during emiction.

Yes ( ) 1 No ( ) 0

b. Pain or discomfort after sexual orgasm (ejaculation) or during sexual intercourse

Yes ( ) 1 No ( ) 0

3. Do you feel pain or discomfort in these parts in the past 1 week?

( ) 0a. Never ( ) 1b. Seldom ( ) 2c. Sometimes

( ) 3d. Most of the time ( ) 4e. Almost always ( ) 5f. Always

4. Which number can best describe “average degree” of your pain or discomfort in the past 1 week?

( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )

0 1 2 3 4 5 6 7 8 9 10

"0" means painless, and increase progressively to "10"; "10" means the most acute pain one can imagine.

II. Emiction

5. In the past 1 week, do you always feel endless urination after emiction?

( ) 0a. Never ( ) 1b. Less than once in 5 times ( ) 2c. Less than half of the time

( ) 3d. About half of the time ( ) 4e. Over half of the time ( ) 5f. Almost always

6. In the past 1 week, do you want to pee within 2 hours after emiction?

( ) 0a. Never ( ) 1b. Less than once in 5 times ( ) 2c. Less than half of the time

( ) 3d. About half of the time ( ) 4e. Over half of the time ( ) 5f. Almost always

III. Effect of symptoms

7. In the past 1 week, does your symptom always affect your job?

( ) 0a. Never ( ) 1b. Hardly ( ) 2c. Sometimes ( ) 3d. Often

8. In the past 1 week, do you always feel your symptom?

( ) 0a. Never ( ) 1b. Hardly ( ) 2c. Sometimes ( ) 3d. Often

9. How do you feel if the symptom in the past week always accompanies you in your future daily life?

( ) 0a. Happy ( ) 1b. Glad ( ) 2c. Satisfied most of the time

( ) 3d. Half satisfied and half dissatisfied ( ) 4e. Dissatisfied most of the time

( ) 5f. Joyless ( ) 6g. Unhappy

Total score:_____ Severity of the patient's disease: Mild□ Medium□ Severe□

★ Score ≤9 is mild, score 10~18 is medium, and score ≥18 is severe.

(2) Changes of the number of white blood cell and lecithin corpuscles in expressed prostatic secretion (EPS).

(3) Finger examination of prostate

Compare changes of texture and tenderness of prostate before and after treatment.

$$\text{Note: Indicator for curative effect} = \frac{\text{Total scores of main symptoms and signs before treatment} - \text{Total scores of main symptoms and signs after treatment}}{\text{Total scores of main symptoms and signs before treatment}} \times 100$$

4. Safety observation

All centers draw 20% cases at random, and carry out safety observation, including:

Blood routine test and urine routine test

Cardiograph, liver function (AST, ALT) and renal function (BUN, Scr)

Adverse events

Safety evaluation

5. Experiment assessment index

Whether it is drop out or not

Compliance

(III)Time point of observation

1. Main symptoms and signs: observe and record main symptoms and signs once respectively at the first day of the first diagnosis, at the end of the 4^{th} week and at the end of the 8^{th} week.

2. All laboratorial examinations of curative effect and safety shall be carried out once respectively before and after treatment (abnormal cases shall go through liver and renal function test again within 7 days after treatment). If the subject is cured and the treatment is stopped in advance, physico-chemical re-examination may be carried out ahead of schedule.

(IV) Evaluation criteria of curative effect and safety

1. Main evaluation criteria of curative effect

(1) Clinical control

i. Indicator for curative effect ≥95%;

ii. The result of EPS examination is normal.

(2) Excellent

i. Indicator for curative effect ≥60%;

ii. WBC number in EPS examination is reduced by ≥60% than that before treatment;

(3) Effective

i. Indicator for curative effect ≥30%;

ii. WBC number in EPS examination is reduced by ≥30% than that before treatment;

(4) Ineffective

i. Indicator for curative effect < 30% or without any change

ii. WBC number in EPS examination is reduced by < 30% or without any change;

2. Evaluation of curative effect on main symptoms

Carry out the analysis of curative effect on falling swell, ache and terminal dribbling of perineal region.

3. Evaluation of curative effect on main test indexes

Carry out the analysis of curative effect on WBC number in EPS examination.

4. Evaluation criteria of safety

Level 1: safe, without any adverse reactions.

Level 2: relatively safe. If adverse reactions occur, the subject doesn't need any handling and can continue to take the medicine.

Level 3: with safety problems and medium adverse reactions. The subject can continue to take the medicine after handling.

Level 4: stop the experiment due to adverse reactions.

5. Criteria of judging the serious extent of adverse events

Mild: the subject is able to bear, and the treatment is not affected. It doesn't need any special disposal, and the recovery of the subject is not affected.

Medium: the subject finds it difficult to bear, needs to withdraw the medicine and stop the experiment, or make some special disposal. The recovery of the subject is affected directly.

Serious: endanger the subject's life; the subject dies or is disabled. Withdraw the medicine immediately or make some special disposal.

VII. Observation of Adverse Events

1. Observation and Record

The investigator should ask patients to faithfully reflect their condition changes after taking the medicine and should avoid induced questions.

Write down any adverse reaction that occurs during the test in the "Table for Adverse Events", track and research the reaction, and record the process and result of dealing with the reaction till the test shows that the condition is back to normal and symptoms and signs disappear. Tracking modes could be hospitalization, outpatient service, home visit, telephone or communication according to the seriousness of adverse reaction.

2. Medical Treatment

When adverse reaction happens, the investigator, basing on patients' condition, decides the measures of diagnoses and treatments and decides whether the observation should be stopped. When a serious adverse event happens, the unit that assumes the clinical research should take necessary treatment at once to protect subject' safety and at the same time notify the monitor.

3. Report

The investigator fills in the “Report of Serious Adverse Events”, respectively reports to Department of Drug Registration of State Drug Administration, Department of Drug Safety and Inspections of State Drug Administration, Provincial Drug Administration, Sponsor and Ethics Committee in 24 hours, and signs and dates the report. The sponsor shall notify the participating institutions in time and make sure that the report procedure complies with relevant laws and statutes.

Emergent situation, including serious adverse reactions, especially the lethal adverse reaction, should be reported to the specialized agency for monitoring adverse drug reactions in the local province, autonomous region or municipality directly under the central government through using the most convenient communication methods (including telephone, fax, express mail service, E-mail and so on).

VIII. Data Management

(I) Medical record for research

As the outpatient medical records in our country are generally held by patients themselves, so “Medical Record for Research” specially used for the clinical trial is designed to integrally save the first-hand data.

“Medical Record for Research” is the original document of clinical subject and should be kept in the hospital. “Medical Record for Research” is the medical record data of outpatient subject and forms the medical record data of hospitalization subject together with hospitalization medical record.

(II) Data Record

1. Requirements for recording the medical record: ①The investigator must write down the medical record when making diagnoses and treatments for the subject and ensure that the data record is timely, complete, exact and true. ②Score the record if correction is needed and use marginal note for the changed data. The investigator makes the signature and marks the data. Original record should not be erased or covered. ③Stick the original assay sheet of the outpatient subject to the Medical Record for Research and stick the original assay sheet of the hospitalization subject to the Hospitalization Medical Record. Assay result of outpatient and hospitalization subject should be filled in the “Physicochemical Examination Result Report” of

the Medical Record for Research.

2. Auditing of Medical Record for Research: When the observation treatment period of each subject finishes, the investigator should submit in time the “Medical Record for Research”, “Information Consent Form” and “Patient Dosage Record Card” to the unit’s main investigators for approve and signature. Deal with the problems found and keep a record.

(III) Data Monitoring

Number of monitors and times of visit should meet the quality control requirements of clinical trial. The monitor audits each Medical Record for Research and fills out each “Monitor Approve Page”.

(IV) Data Processing

1. The monitor seals the completed Medical Record for Research, submits it to the chief unit base project principal and conducts the handing over procedures.

2. The data controller examines the Medical Record for Research in accordance with the clinical trial protocol and fills in the Query List if there’s any question. The investigator answers in written form the questions in the Query List, makes a signature and returns it to the data controller. The Query List should be properly kept.

The chief unit is responsible for creating database; use “double entry”, computer and labor check and lock the database.

IX. Statistical Analysis

1. Statistical Analysis Plan and Statistical Software

1. After the test protocol is fixed, the professional statistician negotiates with main investigators to formulate statistical analysis plan. Use SAS 6.12 statistical software.

2. Selection of Analysis Data Sets

Full Analysis Set: namely, ideal subject set close to intentional analysis principle (the key analysis must includes all subjects) and this data set is gained through elimination which is done among all subjects with the smallest and reasonable method. Estimate the missing value of key variable by carrying the result that is closest to one-time observation forward to the test missing data; number of subject for evaluation of therapeutic efficiency at the end of the test should be equal to that at the beginning.

Per Protocol Set: Accord with testing treatment protocol; major variable can be measured;

baseline variable is not missing; no serious violation against the testing protocol.

Security Set: All subjects that receive treatment for at least one time.

Respectively use Full Analysis Set and Per Protocol Set for clinical symptom score and NIH-CPSI scoring analysis: use Per Protocol Set for demography, other baseline characteristics and therapeutic index analyses.

3. Content of Statistical Analysis

Actual quantity of selected subject in two groups, situation of cases drop out or being eliminated, demography and other baseline characteristics, compliance, therapeutic efficiency analysis and security analysis.

4. Method of Statistical Analysis

Descriptive statistical analysis, qualitative index is expressed by frequency table, percentage or constituent ratio description; qualitative index is expressed by mean, standard deviation, or median, lower quartile (Q1) and upper quartile (Q3) description.

Make contrastive analysis between the two groups, qualitative data adopts chi-square test, Fisher precise probabilistic method, Wilcoxon rank sum test, CMH^2 test and WLS covariance. t test will be used if qualitative data conforms to normal distribution (doing homogeneity test of variances between groups, takes 0.5 as the test level and makes the proofreading t test with Satterthwaite method when the variance is homogeneous) and Wilcoxon rank sum test, Wilcoxon signed rank sum test and GLM covariance will be used if does not conform to normal distribution; Hypothesis test uses two-sided test in a unified way, presents Test Statistic and the corresponding P value and considers $P \leqslant 0.05$ as statistical significance.

X. Ethical Principle

(I) Main investigators and the sponsor agree on the clinical trial protocol and carry out the protocol after the protocol being approved by the ethics committee. If the protocol is emended during the clinical trial, the emended protocol can be carried out only after being approved by the ethics committee. If important new data relating to test medicine is found, modify the Information Consent Form and submit it to the ethics committee for approval and again obtain subject’s agreement.

All clinical trial centers agree that under normal circumstances the research project is examined by chief unit’s ethics committee and filed by ethics committees of centers. If necessary (for

example, serious adverse event occurs), ethics committee of each center should immediately hold a meeting for the examination and notify other ethics committees of the examination conclusion.

(II) Benefit and Risk: Benefit that the subject can get from the clinical trial: The subject will get effective clinical treatment and medication of favorable security, and especially the symptom will be improved by using the test medicine; the subject can also receive medical treatment for free.

Risks that the subject may be confronted with: The test medicine may have side effect or adverse reaction such as gastrointestinal problems. Medical treatment solutions have been formulated for the known side effect or adverse reaction, including that the investigator is entitled to stop the clinical trial on the basis of his or her own judgment.

(III) Recruitment of Subject: Recruit hospital subject and release relevant information by putting up a notice→registration of interested candidates→read research introduction→physical examination of postulants→selection→the eligible sign the Information Consent Form→select subject→random grouping. Refer to the appendix for the notice and the research introduction and submit them to the ethics committee for examination.

(IV) Medical Treatment and Protection for Subject: Investigators of test centers take charge of the medical treatment for the subject, make decisions relating to clinical trial and make sure that the subject will receive proper treatment when adverse event occurs during the test.

The sponsor should study the serious adverse event with the investigator at once, take necessary measures to ensure the subject's safety and interests, duly report to Drug Safety and Inspections Department and at the same time inform other investigators involved in the clinical trial which uses the same medicine of the adverse event.

Treatment expense and economic compensation due to relevant injury or death of the subject should be borne by the sponsor. The sponsor should provide the investigator with legal and economic guarantee, but not including injury or death caused by medical negligence.

During the clinical trial, the subject will get test medicine and receive physicochemical examination for free; the subject will be compensated for the inconvenience of transportation and examination and loss of working time caused by participation in the clinical trial. The subject will get cost-free treatment if an adverse event concerned with the test medicine occurs.

(V) Subject Privacy Protection: Only investigators participating in the clinical trial and monitors have access to the subject's personal treatment records. "Investigator Statement" and "Promise of Privacy" signed by them stipulate the content that should be kept confidential. The drug safety

and inspection department has the right to inspect the clinical trial record. Use “data anonymity” for data processing and omit the personal recognizable information of the subject. Treatment record of subject should be kept in the data file room of the National Base for Drug Clinical Trial.

(VI) Course of Informed Consent: When selecting qualified postulants, the investigator must clearly explain the conditions relating to the clinical trial, including test purpose, test procedure, possible benefit and risk, subject’s right and obligation and so forth. The subject gets a full understanding, has enough time for consideration, expresses agreement after all questions brought forward being satisfactorily replied and signs the “Information Consent Form”, and then the clinical trial can start. When the patient signs the “Information Consent Form”, the doctor should give his or her telephone or cell phone number to the patient, so the patient can get in contact with the doctor when there’s any change of illness state.

XI. Statistical Results

CI	Confidence Interval
CMH	Cochran-Mantel-Haenszel Test
F	F-statistic (variance analysis result)
ITT	Intent To Treat
Max	Maximum Value
Min	Minimum Value
PP	Per Protocol
SD	Standard Deviation
01	Beijing Hospital
02	China-Japan Friendship Hospital
03	General Hospital of People’s Liberation Army
04	The First Affiliated Hospital of Zhejiang Chinese Medical University
05	Sir Run Run Shaw Hospital Affiliated to School of Medicine, Zhejiang University (inconsistent with random principle, its cases aren’t included in statistics.)
06	Guangxing Hospital Affiliated to Zhejiang Chinese Medical University

1. Case analysis

The study has 220 cases in the planned group and 193 cases in the actual group, while the

remaining 27 cases are not included in the study. The group of Center 5 is inconsistent with random principle, so its 11 cases aren't included in curative effect statistics. There are 140 cases in medicine group in statistics of curative effects, 1 drop out case, 12 rejected cases and 127 actually finished cases; there are 42 cases in control group, 1 drop out case, 3 rejected cases and 38 actually finished cases.

Table 1-1 Case Distribution

	Medicine group N (%)	Control group N (%)
Aggregate		
Cases in the group	140	42
Finished case	127(90.71)	38(90.48)
Drop out case	1(0.71)	4(9.52)
Rejected case	12(8.57)	0(0.00)
Beijing Hospital		
Cases in the group	27	9
Finished case	27(100.00)	9(100.00)
Drop out case	0(0.00)	0(0.00)
Rejected case	0(0.00)	0(0.00)
China-Japan Friendship Hospital		
Cases in the group	24	8
Finished case	20(83.33)	5(62.50)
Drop out case	0(0.00)	0(0.00)
Rejected case	4(16.67)	3(37.50)
Beijing 301 Hospital		
Cases in the group	22	4
Finished case	20(90.91)	11(91.67)
Drop out case	1(2.70)	1(8.33)
Rejected case	4(10.81)	0(0.00)
The First Affiliated Hospital of Zhejiang Chinese Medical University		
Cases in the group	37	12
Finished case	32(86.49)	11(91.67)
Drop out case	1(2.70)	1(8.33)
Rejected case	4(10.81)	0(0.00)
Guangxing Hospital of Zhejiang Chinese Medical University		
Cases in the group	31	9
Finished case	28(90.32)	9(100.00)
Drop out case	0.(0.00)	0(0.00)
Rejected case	3(9.68)	0(0.00)

Table 1-2 Detailed List of Drop out and Rejected Cases

Center	Group	Medicine No.	Reason for Discontinuation	Kind of Discontinuation

The First Affiliated Hospital of Zhejiang Chinese Medical University	Control Group	102	Lost follow-up	Drop out
The First Affiliated Hospital of Zhejiang Chinese Medical University	Medicine Group	103	Lost follow-up	Drop out
Beijing 301 Hospital	Medicine Group	55	False Acceptance	Rejected
Beijing 301 Hospital	Medicine Group	60	False Acceptance	Rejected
China-Japan Friendship Hospital	Medicine Group	69	False Acceptance	Rejected
China-Japan Friendship Hospital	Control Group	70	False Acceptance	Rejected
China-Japan Friendship Hospital	Control Group	75	False Acceptance	Rejected
China-Japan Friendship Hospital	Medicine Group	76	False Acceptance	Rejected
China-Japan Friendship Hospital	Medicine Group	78	False Acceptance	Rejected
China-Japan Friendship Hospital	Control Group	85	False Acceptance	Rejected
China-Japan Friendship Hospital	Medicine Group	97	False Acceptance	Rejected
The First Affiliated Hospital of Zhejiang Chinese Medical University	Medicine Group	124	False Acceptance	Rejected
The First Affiliated Hospital of Zhejiang Chinese Medical University	Medicine Group	125	False Acceptance	Rejected
The First Affiliated Hospital of Zhejiang Chinese Medical University	Medicine Group	147	False Acceptance	Rejected
Guangxing Hospital of Zhejiang Chinese Medical University	Medicine Group	196	False Acceptance	Rejected
Guangxing Hospital of Zhejiang Chinese Medical University	Medicine Group	204	False Acceptance	Rejected
Guangxing Hospital of Zhejiang Chinese Medical University	Medicine Group	220	False Acceptance	Rejected

2. Analysis of Comparability

General conditions of all pre-treatment groups are comparable, including age, height, weight, breath and blood pressure, etc. Other things such as urination and NIH-CPSI scores are also comparable. There are no marked differences between the base line of medicine group and base line of control group before they are included in the group.

Table 2-1 Age (years old)

Aggregate	Medicine Group	Control Group	Statistics	P Value
N	127	38		
Mean ± SD	35.90(8.60)	34.34(8.63)		

Min~Max	19.01~54.78	21.96~49.36	0.958	0.3291
Median	34.69	32.67		

Table 2-2 General Information

Item	Medicine Group	Control Group	Test Statistic	P Value
Weight (kg)				
N (Missing)	127(0)	38(0)	0.001(F Value)	0.9723
Mean (SD)	69.53(12.46)	69.45(10.01)		
Min-Max	49.00-170.00	52.00-92.00		
Median	69.00	67.00		
Height (cm)				
N (Missing)	127(0)	38(0)	0.114(F Value)	0.7356
Mean (SD)	170.79(11.87)	170.12(5.07)		
Min-Max	48.00-183.00	161.00-184.00		
Median	172.00	170.00		
Body Temperature				
N (Missing)	127(0)	38(0)	0.279(F Value)	0.5980
Mean (SD)	170.79(11.87)	170.12(5.07)		
Min-Max	48.00-183.00	161.00-184.00		
Median	172.00	170.00		
Breath (times)				
N (Missing)	127(0)	38(0)	0.930(Rank sum)	0.3349
Mean (SD)	18.10(1.54)	18.26(1.39)		
Min-Max	10.00-23.00	15.00-20.00		
Median	18.00	18.00		
Pulse (times)				
N (Missing)	127(0)	38(0)	0.603(Rank sum)	0.4373
Mean (SD)	74.52(7.15)	75.45(6.60)		
Min-Max	54.00-100.00	61.00-100.00		
Median	72.00	74.50		
Diastolic Pressure (mmHg)				
N (Missing)	127(0)	38(0)	3.154(F Value)	0.0776
Mean (SD)	100.46(22.54)	93.00(23.26)		
Min-Max	60.00-140.00	60.00-135.00		
Median	110.00	80.00		
Systolic Pressure (mmHg)				
N (Missing)	127(0)	38(0)		
Mean (SD)	97.25(22.67)	100.45(22.98)		
Min-Max	58.00-140.00	70.00-140.00		
Median	85.00	110.00		
Course of Disease (month)				
N (Missing)	127(0)	38(0)	0.137(F Value)	0.7121
Mean (SD)	24.20(33.030	22.11(20.97)		

Min-Max	2.00-242.00	3.00-84.00
Median	12.00	13.00

Table 2-3 Course of Disease (month)

Aggregate	Medicine Group	Control Group	Mean Difference	P Value
N	135	41		
Mean ± SD	23.87(32.21)	24.29(25.38)		
Min~Max	2.00-242.00	3.00-120.00	0.006	0.9382
Median	14.00	13.00		

Table 2-4 NIH-CPSI Total Score

	Medicine Group N (%)	Control Group N (%)	Statistics	P Value
Mild	0	0		
Moderate	39(30.71)	11(28.95)	0.2042	0.8382
Severe	88(69.29)	17*71.05)		
Total	127	38		

3. Assessment of Obedience

Except drop out cases, other finished cases have good obedience.

Table 3-1 Assessment of Obedience

Aggregate	Medicine Group N (%)	Control Group N (%)	Statistics	P Value
Bad obedience	0(0.00)	0(0.00)		
Good obedience	127(100.00)	38(100.00)	-	-
Total	127	38		

During the experiment, drug combination doesn’t occur among all patients.

4. Analysis of Curative Effects

4.1 NIH-CPSI curative effects

Total effective rate of medicine group is 83.46% (n=127), and total effective rate of control group is 86.84 (n=38). The comparison between medicine group and control group has no statistical significance. Medicine group and control group have basically the same curative effects. Differences among all centers have no marked significance.

Table 4-1 Judgment and Analysis of NIH-CPSI Curative Effects among All Centers

	N	Clinical control	Excellent	Effective	Ineffective	Total excellent effective	Total effective rate %

Aggregate								
	Medicine group	127	1	27	78	21	22.04	83.46
	Control group	38	0	4	29	5	10.52	86.84
Beijing Hospital								
	Medicine group	27	1	5	19	3	22.22	88.89
	Control group	9	0	2	7	0	22.22	100
China-Japan Friendship Hospital								
	Medicine group	20	0	8	9	2	40	90.00
	Control group	5	0	2	2	1	40	80.00
Beijing 301 Hospital								
	Medicine group	20	0	8	8	4	40	80.00
	Control group	4	0	0	4	0	0	100.00
The First Affiliated Hospital of Zhejiang Chinese Medical University								
	Medicine group	32	0	2	22	8	6.25	75.00
	Control group	11	0	0	8	3	0	72.73
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University								
	Medicine group	28	0	4	20	4	14.28	85.71
	Control group	9	0	0	8	1	0	88.89

Test group: χ^2=0.303 P=0.859

Control group: χ^2=0.044 P=0.978

Note: Total excellent effective rate= excellent effective cases/total cases×100%; total effective rate=(excellent effective cases +effective cases) /total cases×100%.

4.2 Integral Analysis of NIH-CPSI Scores

4.2.1 Analysis of NIH-CPSI score changes among all centers

Analysis of NIH-CPSI score changes among all centers: medicine group drops by 9.78(n=127); control group drops by 8.61(n=38). Statistical analysis finds no marked differences among the different values from multi-center.

Table 4-4 Analysis of NIH-CPSI scores (take medicine for 8 wk) and pre-treatment changed value (after-before) from multi-center

Item	Medicine Group	Control Group	Test Statistic	P Value
CPSI score difference				
N	127	38	1.755(F Value)	0.1872
Mean ± SD	-9.78(4.90)	-8.61(4.30)		
Min~Max	-27.00-2.00	-17.00-0.00		
Median	-9.00	-8.00		
CPSI score difference				
Beijing Hospital				
N	27	9	0.021(F Value)	0.8856

Mean(SD)	-11.89(4.04)	-12.11(3.79)		
Min-Max	-20.00-4.00	-17.00-5.00		
Median	-13.00	-13.00		
CPSI score difference				
China-Japan Friendship Hospital				
N	20	5	0.661(F Value)	0.6167
Mean(SD)	-12.30(4.71)	-10.21(5.61)		
Min-Max	-22.00-5.00	-24.00-3.00		
Median	-12.00	-12.00		
CPSI score difference				
Beijing 301 Hospital				
N	20	4	0.032(F Value)	0.8593
Mean(SD)	-12.10(6.360	-11.50(4.20)		
Min-Max	-27.00-1.00	-17.00-7.00		
Median	-12.00	-11.00		
CPSI score difference				
The First Affiliated Hospital of Zhejiang Chinese Medical University				
N	32	11	1.459(F Value)	0.2344
Mean(SD)	-6.57(2.67)	-7.82(3.60)		
Min-Max	-12.00-1.00	-14.00-3.00		
Median	-6.00	-7.00		
CPSI score difference				
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University				
N	28	9	1.329(F Value)	0.2568
Mean(SD)	-7.71(3.72)	-6.22(1.79)		
Min-Max	-17.00-2.00	-9.00-4.00		
Median	-7.00	-6.00		

Table 4-5 Variance Analysis Form of NIH-CPSI Scores from Multi-center (take medicine for 8 wk)

	df	SS	MS	F	P
Total variation	162	3704.74			
Group	1	22.98	22.98	1.28	0.2589
Center	4	854.89	213.73	11.94	＜0001
Error	157	2809.90	17.90		

4.2.2 Analysis of change rate of NIH-CPSI scores from multi-center

Analysis of change rate of NIH-CPSI scores: medicine group drops by 45.15% (n=127); control group drops by 40.09% (n=38). Statistical analysis finds no marked differences between the pre-treatment and after-treatment change rates from multi-center.

Table 4-6 Analysis of NIH-CPSI Scores (take medicine for 8 wk) and Pre-treatment Change Rate (after-before) from Multi-center

Item	Medicine Group	Control Group	Test Statistic	P Value
Change rate of CPSI scores				
N	127	38	1.755(F Value)	0.1872
Mean ± SD	45.15(18.04)	40.09(15.54)		
Min~Max	-20.00-95.00	0.00-70.00		
Median	45.00	38.46		
Change rate of CPSI scores				
Beijing Hospital				
N	27	9	0.032(F Value)	0.8596
Mean ± SD	48.18(14.92)	49.17(12.37)		
Min~Max	12.50-71.43	35.71-68.42		
Median	51.85	47.37		
Change rate of CPSI scores				
China-Japan Friendship Hospital				
N	20	5	0.382(F Value)	0.5310
Mean ± SD	55.41(17.90)	51.68(30.51)		
Min~Max	27.27-95.00	20.00-90.00		
Median	58.71	55.00		
Change rate of CPSI scores				
Beijing 301 Hospital				
N	20	4	0.461(F Value)	0.5044
Mean ± SD	51.12(22.89)	43.04(12.15)		
Min~Max	4.17-81.82	31.82-54.84		
Median	55.84	42.75		
Change rate of CPSI scores				
The First Affiliated Hospital of Zhejiang Chinese Medical University				
N	32	11		
Mean ± SD	37.82(12.80)	40.53(12.48)		
Min~Max	9.09-60.00	18.75-42.86		
Median	38.68	38.89		
Change rate of CPSI scores				
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University				
N	28	9	0.618(F Value)	0.4372
Mean ± SD	38.51(17.06)	33.85(7.99)		
Min~Max	-20.00-68.18	15.85-42.86		
Median	37.09	34.78		

Table 4-7 Variance Analysis Form of NIH-CPSI Scores from Multi-center (take medicine for 8 wk)

	df	SS	MS	F	P	
Total variation	162	50046.27				Total variation
Group	1	540.81	540.81	1.93	0.1670	Group
Center	4	5253.39	1313.35	4.68	0.0013	Center

Error	157	44046.33	280.55	Error

4.2.3 Diachronic analysis of NIH-CPSI scores

Table 4-8 Diachronic Analysis of NIH-CPSI Scores

Item	Medicine Group	Control Group	Test Statistic	P Value
CPSI score-before				
N	127	38	0.040(F Value)	0.8424
Mean ± SD	21.14	21.34		
Min~Max	10.00-37.00	12.00-32.00		
Median	21.00	20.00		
CPSI score-4 weeks				
N	127	38	0.679(F Value)	0.4111
Mean ± SD	15.79	16.55		
Min~Max	1.00-31.00	9.00-36.00		
Median	15.00	16.00		
Pairing t (P)	13.98(＜0.0001)	7.31(＜0.0001)		
CPSI score-8 weeks				
N	127	38		
Mean ± SD	11.45(4.61)	12.74(4.76)		
Min~Max	1.00-28.00	6.00-26.00		
Median	11.00	11.50		
Pairing t (P)	22.30(＜0.0001)	12.33(＜0.0001)		

Table 4-10 Diachronic Changes of NIH-CPSI Scores and Baseline Difference (after-before)

Item	Medicine Group	Control Group	Test Statistic	P Value
CPSI score difference (4 weeks- before)				
N	127	38	0.515(F Value)	0.4738
Mean ± SD	-5.35(4.32)	-4.79(4.04)		
Min~Max	-21.00-5.00	-14.00-8.00		
Median	-5.00	-5.00		
CPSI score difference (8 weeks-before)				
N	127	38		
Mean ± SD	-9.78(4.90)	-8.61(4.30)		
Min~Max	-27.00-2.00	-17.00-0.00		
Median	-9.00	-8.00		

5. Comparison between WBC microscopic examination counting and changes of the number of lecithin corpuscles.

Table 5-1 Comparison of Curative Effects of WBC Microscopic Examination Counting

Group	Clinical Control (%)	Excellent (%)	Effective (%)	Ineffective (%)	Comparison between Groups
Test group	6(4.72%)	38(29.92%)	63(49.61%)	20(15.74%)	X^2=0.22
Control group	3(7.89%)	5(13.16%)	25(65.79%)	5(13.16%)	P＞0.05

Compare the reduction of WBC microscopic examination counting before and after treatment.

Effective rate of test group is 84.25%, and effective rate of control group is 86.48%. There is no obvious difference between these two groups.

Table 5-2 Comparison of Changes of the Number of Lecithin Corpuscles

Group	Number of Cases	Before treatment		After treatment		χ^2	p
		Normal number	Abnormal number	Normal number	Abnormal number		
Test group	127	3	124	52	75	5.337	0.2518
Control group	38	2	36	11	27		

Results show that: medicine group and control group somewhat change WBC microscopic examination counting and the number of lecithin corpuscles. That is to say, both can reduce the number of WBC to a certain extent, so as to cure prostatitis.

7. Safety Analysis

7.1 Laboratory examination

Table 7-1 Overall List of Safety Index Normal/Abnormal and Abnormal/Abnormal before and after Treatment

	N (Deletion)	Normal/ Normal	Normal/Abnormal (Rate of abnormality %)	Abnormal/ Normal	Abnormal/ Abnormal
WBC					
Medicine group	22	21（95.45）	0(0.00)	1(4.55)	0(0.00)
Control group	14	13（92.86）	0(0.00)	1(7.14)	0(0.00)
RBC					
Medicine group	22	22（100.00）	0(0.00)	0(0.00)	0(0.00)
Control group	14	14（100.00）	0(0.00)	0(0.00)	0(0.00)
HB					
Medicine group	22	18（81.82）	0(0.00)	1(4.55)	3（13.64）
Control group	14	14（100.00）	0(0.00)	0(0.00)	0（0.00）
PLT					
Medicine group	22	21(95.45)	0(0.00)	0(0.00)	1（4.55）
Control group	14	100(0.00)	0(0.00)	0(0.00)	0（0.00）
Urine WBC					
Medicine group	22	20(90.91)	0(0.00)	2(9.09)	0(0.00)
Control group	14	14(100.00)	0(0.00)	0(0.00)	0(0.00)
Urine RBC					
Medicine group	22	21(95.45)	0(0.00)	2(4.55)	0(0.00)
Control group	14	14(100.00)	0(0.00)	0(0.00)	0(0.00)
Urine protein					
Medicine group	22	21(95.45)	0(0.00)	1(4.55)	0(0.00)
Control group	14	14(100.00)	0(0.00)	0(0.00)	0(0.00)
ALT					
Medicine group	22	18（81.82）	0(0.00)	2(9.09)	2（9.09）
Control group	14	14（100.00）	0(0.00)	0(0.00)	0（0.00）
AST					

Medicine group	22	22（90.91）	0(0.00)	2（9.09）	0(0.00)
Control group	14	14（100.00）	0(0.00)	0（0.00）	0(0.00)
BUN					
Medicine group	22	22（100.00）	0(0.00)	0(0.00)	0(0.00)
Control group	14	14（100.000	0(0.00)	0(0.00)	0(0.00)
CR					
Medicine group	22	22(100.00)	0(0.00)	0(0.00)	0(0.00)
Control group	14	14(100.00)	0(0.00)	0(0.00)	0(0.00)
Cardiogram					
Medicine group	30	27(90.00)	0(0.00)	0(0.00)	3（10.00）
Control group	10	10(100.00)	0(0.00)	0(0.00)	0（0.00）

Table 7-2 List of Abnormal Values of WBC Determination before Treatment (before taking medicine) and after Treatment (take medicine for 8 wk)

Center	Medicine No.	Group	Value before medicine ($\times 10^9$/L)	Judgment before medicine	Value after medicine ($\times 10^9$/L)	Judgment after medicine	Note
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	210	Medicine group	3.9	Abnormal	5.6	Normal	
Beijing Hospital	12	Control group	10.2	Abnormal	10.2	Normal	

Table 7-3 List of Abnormal Values of HB Determination before Treatment (before taking medicine) and after Treatment (take medicine for 8 wk)

Center	Medicine No.	Group	Value before medicine (g/L)	Judgment before medicine	Value after medicine (g/L)	Judgment after medicine	Note
Beijing 301 Hospital	71	Medicine group	177	Abnormal	175	Abnormal	
Beijing 301 Hospital	73	Medicine group	169	Abnormal	167	Abnormal	
Beijing 301 Hospital	74	Medicine group	161	Abnormal	168	Abnormal	
Beijing 301 Hospital	88	Medicine group	165	Abnormal	153	Normal	

Table 7-4 List of Abnormal Values of ALT Determination before Treatment (before taking medicine) and after Treatment (take medicine for 8 wk)

Center	Medicine No.	Group	Value before medicine (U/L)	Judgment before medicine	Value after medicine (U/L)	Judgment after medicine	Note
Beijing Hospital	2	Medicine	43	Abnormal	44	Abnormal	Effect

		group					of diet
China-Japan Friendship Hospital	71	Medicine group	42	Abnormal	38	Normal	
China-Japan Friendship Hospital	73	Medicine group	48	Abnormal	61	Abnormal	Effect of diet
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	210	Medicine group	50	Abnormal	27	Normal	

Table 7-5 List of abnormal values of AST determination before treatment (before taking medicine) and after treatment (take medicine for 8 wk)

Center	Medicine No.	Group	Value before medicine (U/L)	Judgment before medicine	Value after medicine (U/L)	Judgment after medicine	Note
Beijing Hospital	2	Medicine group	44	Abnormal	31	Normal	
China-Japan Friendship Hospital	71	Medicine group	43	Abnormal	32	Normal	

Table 7-6 List of Abnormal Values of Cardiogram before Treatment (before taking medicine) and after Treatment (take medicine for 8 wk)

Center	Medicine No.	Group	Value before medicine	Judgment before medicine	Value after medicine	Judgment after medicine	Note
Beijing 301 Hospital	61	Medicine group	Pre-excitation syndrome	Abnormal	Pre-excitation syndrome	Abnormal	Same as that before treatment
China-Japan Friendship Hospital	71	Medicine group	Incomplete right bundle branch block	Abnormal	Incomplete right bundle branch block	Abnormal	Same as that before treatment
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	101	Medicine group	Significant left deviation of electrical axis	Abnormal	Significant left deviation of electrical axis	Abnormal	Same as that before treatment

7.2 Adverse Event

No adverse event happens in medicine group and control group.

7.3 Safety analysis

Table 7-7 General Conditions of Safety Analysis

Item	Cases Number	Unit	Before treatment $\chi \pm S$	After treatment $\chi \pm S$	t	P
ALT	32	U/L	25.80±10.98	24.48±11.76	0.76	0.4547

AST	32	U/L	23.57±9.26	21.40±5.53	1.43	0.1641
Cr	32	umol/L	70.65±16.75	73.62±16.25	-1.24	0.2253
BuN	32	umol/L	5.37±1.07	5.48±1.08	-0.68	0.5003

XII. Discussion

1. Two groups of cases are compared from aspects of age, course of disease and NIH-CPSI score distribution. Statistical examination shows that P＞0.05, and there is no obvious difference. These two groups have comparability.

2. According to observation of overall curative effects, total effective rate of medicine group is 83.46%, and total effective rate of control group is 86.48%. Statistical examination shows that P ＞0.05, and there is no obvious difference. It suggests that overall curative effects in all centers are basically identical.

3. Compare overall curative effects in all centers. Statistical examination shows that P＞0.05, and there is no obvious difference. It suggests that overall curative effects in all centers are basically identical.

4. Compare NIH-CPSI index curative effects. Statistical examination shows that P＞0.05, and there is no obvious difference. It suggests that overall curative effects in all centers are basically identical.

5. Compare the changes of WBC counting. Medicine group and control group contribute somewhat to reducing WBC counting. There is no obvious difference between medicine group and control group. Then compare the changes of lecithin corpuscles, and find that medicine group contributes somewhat to reducing lecithin corpuscles, and there is no obvious difference between the curative effects of medicine group and that of control group.

6. Compare some patients' liver function and renal function before and after treatment. Statistical examination shows that P＞0.05, and there is no obvious difference. It suggests that this experimental medicine has no effect on liver function and renal function. (Refer to Table 8-7)

7. Observe the adverse reactions: there is no adverse reaction when 165 cases of patients take this medicine.

XIII. Conclusion

Clinical trials of Pule'an Tablet and Cernilton show that it is safe and effective to treat prostatitis with Pule'an Tablet. Through NIH-CPSI score analysis and analysis of changes before and after treatment, we find that the comparison between the curative effect of medicine group and that of

control group doesn’t have statistical significance, and curative effect of medicine group is basically identical with that of control group. Both have certain curative effect on improving typical symptoms of prostatitis; both reduce WBC number and lecithin number in varying degree. Moreover, their differences don’t have statistical significance, which means that both curative effects are basically identical. There aren’t severe adverse reactions in the experiment. Abnormality in blood and urine routine tests and tests of liver and renal function has been examined again, or given reasonable explanations.

Experimental results show that the curative effect and safety of Pule’an Tablet is reliable in treating prostatitis. This conclusion coincides with application reality of this product. This experiment verifies above viewpoint with normative clinical observations.

Summary Report on Clinical Trial of Qianliekang® Pule'an Tablet in Prostatics Treatment

Unit in Charge of the Clinical Research:

Beijing Hospital

Units Participating in the Clinical Research:

China-Japan Friendship Hospital

General Hospital of the People's Liberation Army (301 Hospital)

The First Affiliated Hospital of Zhejiang Chinese Medical University

Guangxing Hospital Affiliated to Zhejiang Chinese Medical University

Sir Run Run Shaw Hospital Affiliated to School of Medicine of Zhejiang University

Unit in Charge of Statistics:

Medical Statistics Teaching and Research Section of China PLA Postgraduate Medical School (General Hospital of PLA)

Applying Unit: Zhejiang Conba Pharmaceutical Co., Ltd.

June, 2007

Summary Report on Clinical Trial of Qianliekang® Pule'an Tablet in Prostatics Treatment

In order to apply for protection (continued) of TCM product Qianliekang® Pule'an Tablet according to the file Zhe Zhong Bao Lin (2005) No.5 issued by Zhejiang Food and Drug Administration, Pharmacology Clinical Trial Base at Beijing Hospital of Ministry of Health, which was entrusted to be in charge of the clinical research of the medicine, together with the participating hospitals, including China-Japan Friendship Hospital, The General Hospital of General Hospital of PLA (301 Hospital), The First Affiliated Hospital of Zhejiang Chinese Medical University (hereinafter referred to as First Affiliated Hospital of ZCMU), Guangxing Hospital Affiliated to Zhejiang Chinese Medical University (hereinafter referred to as Guangxing Hospital) and Sir Run Run Shaw Hospital, Affiliated to School of Medicine of Zhejiang University (hereinafter referred to as Sir Run Run Shaw Hospital), made clinical observation and trial on Qianliekang® Pule'an Tablet produced by Zhejiang Conba Pharmaceutical Co., Ltd. for a period from Sept. 2006 to June 2007. Proscar was used as comparative medicine for prostatitis indication in the clinical observation. The summary of the result is as below:

I. Trial Purpose

Main purpose: to evaluate clinical efficacy of Pule'an tablet in chronic prostatitis treatment by pre-treatment observation of the change in NIH-CPSI score, the main symptoms and the physical sign scores. Minor purpose: to observe the change in number of white blood cells and small partials of lecithin through EPS microscopical examination; ultrasound diagnosis of prostate and change of residual urine volume

Observe the function of the heart, liver and kidney as well as the possible adverse accidents to evaluate the safety of the tablet.

II. Design of Trial and Grouping Method

1. Trial Design Types: Random, open and parallel comparison design, non-inferiority test.

2. Trial Design Principle

(1) Cases Load: 260 cases, 195 cases for trial group; 65 cases for control group

(2) Grouping method: Central stratified randomization and blocking randomization with

proportion of 3: 1. SAS statistics analysis system was used in random arrangement of the 260 cases in treatment (investigational new drug and control drug), that is, list 001~260 corresponding treatment allocation (attached with randomization project). Please refer to Table 1 for distribution plan of every center. This trial is jointly finished by 5 hospitals.

(3) Control drug: Finasteride Tablets (5 mg). Reason: Prostate Tablet has indication similar to that of Pule'an tablet and is a comparative drug with recognized curative efficacy in China. Thus it meets the requirement of comparable product with well-recognized efficacy

III. General Information

233 outpatient and inpatient male patients with prostatitis, aged between

50-80, were selected as observation objects, of which 175 cases were for trial group, 58 were for control group.

In trial group, the average age was 68.33 ranging from oldest age of 79.82 to youngest age of 50.22 with median age of 69.64; duration of symptom was 61.43 in average ranging from minimum 6 months to maximum 247 months with median 38 months.

In control group: the average age was 66.10 ranging from oldest age of 80.00 to youngest age of 33.90 with median age of 66.48; duration of symptom was 52.01 months ranging from minimum 3 months to maximum 242 months with median of 36 months.

IV. Standards for Case Selection

(I) Diagnosis Standard

1. Diagnosis standard of west medicine on benign prostatic hyperplasia (BPH) (established according to "Recommendations of International Coordination Committee on the Diagnosis and Treatment of Prostatic Patients"):

①Male, above 50 years old;

②Dysuria history: urinary hesitancy, time-consuming and painstaking, small and weak urinary stream, sensation of residual urine, nocturia and even urinary incontinence.

③Rectal examination: two lateral lobes of prostate have enlarged, and central fissure becomes shoal or disappear.

④B-ultrasonic examination: the volume of prostate increases, or there are uneven light spots, or there is residual urine in the bladder. The volume of prostate is ＞20cm^3.

⑤Measurement of urine flow rate: urine volume＞150 milligram, and maximum flow rate ＜15

ml/second.

If ①, ②, ④, ⑤ and another item are obtained, it can be diagnosis as benign prostatic hyperplasia (BPH).

2. Grading standards of severity of the disease (established according to "Recommendations of International Coordination Committee on the Diagnosis and Treatment of Prostatic Patients"):

According to International Prostate Symptoms Scores (I-PSS) and evaluating method of quality of life, urinary symptom is divided into 6 grades from 0 to 5. Overall grading range is 0~35, shown with S0~35. Quality of life has 7 grades from 0 to 6, shown with L 0~6.

International Prostate Symptoms Scores (I-PSS)

	None	Less than 1/5	Less than 1/2	About 1/2	More than 1/2	Almost always
Do you feel endless urination after emiction in the last 1 month	0	1	2	3	4	5
Do you want to pee within 2 hours after emiction in the last 1 month?	0	1	2	3	4	5
Stop and start time after time during emiction in the last 1 month	0	1	2	3	4	5
Cannot wait to pee in the last 1 month	0	1	2	3	4	5
Do you feel urinary stream is smaller in the last 1 month?	0	1	2	3	4	5
Do you feel difficult to pee in the last 1 month	0	1	2	3	4	5
Times of nocturia in the last 1 month	None	Once	Twice	Three times	Four times	Five times
	0	1	2	3	4	5
IPSS total score S=						

The effects of urinary symptom on quality of life

If present urinary symptom continues, how do you feel about your life quality in the future?	Very good	Good	Satisfied most of the time	Half satisfied and half dissatisfied	Dissatisfied most of the time	Unhappy	Miserable
	0	1	2	3	4	5	6
Quality of life index L=							

(II) Inclusion Criteria

1. Male, 50~80 years old;

2. I-PSS score is 8~19, maximum flow rate is 15 ml/second, the volume of prostate is ＞20cm^3, and residual urine volume is ＜60ml.

3. In the last 1 week, the patient hasn't used any Chinese and western medicines to treat prostatic

hyperplasia.

4. Give informed consent, and be willing to take part in the test. The signing of “Information Consent Form” shall conform to GCP regulations.

(III) Exclusion Criteria

1. Below 50 years old or above 80 years old;

2. Neurogenic bladder diseases caused by combined lumbar intervertebral disc prolapse, spinal stenosis, major operation in lower abdomen, severe diabetes and so on.

3. Neoplasm in bladder.

4. Interureteric ridge.

5. Hypertrophy of verumontanum.

6. Bladder neck sclerosis.

7. Prostatic cancer and so on.

8. Those with combined impaired renal function, and I-PSS score is ＜8 or ＞19.

9. After onset of the disease this time, the patient has used other Chinese and western medicines to treat prostatic hyperplasia.

10. The patient has serious primary cardiovascular disease, hepatopathy, nephropathy, lung disease or other serious diseases that affect the patient’s survival, for example, tumor or AIDS. For example, ①renal (serum creatinine) dysfunction and/or albuminuria is＞+. ②ALT exceeds normal value. ③ arrhythmia of clinical significance.

11. The disabled patients as stated in laws.

12. The patient may have or actually have alcohol and drug abuse history; or according to researchers’ judgment, the patient has other diseases that reduce the possibility of inclusion or complicate the inclusion. For example, the patient’s working environment is changed frequently, which easily leads to loss of follow-up.

13. The patient is taking part in clinical trials of other medicines.

14. Those that have an allergy to pollen.

(IV) Drop out case and standard of reject

1. Conditions for subjects to quit or cease the trial

(1) In case of allergic reaction or serious adverse events, the doctor should determine to stop the clinical trial subject, and this case of clinical trial shall be ceased.

(2) In case of deterioration during the course of disease, the doctor determines to stop the clinical

trial subject, and this case of clinical trial shall be ceased. This case shall be regarded to be ineffective case.

(3) If the patient is unwilling to continue this clinical trial during the process, and make a request to the responsible doctor to quit the clinical trial, this case can be stopped.

2. Conditions for premature termination of the trial

(1) Serious adverse events occur during the trial;

(2) During the trial, the curative effect of experimental drug is found to be too bad, and has no clinical value.

(3) Major deviations occur in the design or implementation of clinical trial projects, so it is difficult to evaluate drug effects.

(4) Due to lack of fund or other reasons, the sponsor wants to terminate the clinical trial in advance.

In case of premature termination of the trial, all study parties shall be notified in time.

3. Drop out and disposal of cases

(1) Standard of drop out: due to some reasons, those subjects, who give informed consent and are qualified to participate the random trial, don’t finish course of treatment and observation period stated in this project. In this case, they shall be regarded as drop out cases. However, this doesn’t include subjects who are cured and stop the treatment in advance.

(2) Disposal of drop out cases

A. After the subject is drop out, investigators shall try their best to contact the subject by paying a visit, follow-up with a reservation, telephone or mails and other ways, inquire reasons, record the time of the last dosage, and finish evaluation projects as much as possible.

B. If the subject quits due to allergy, other adverse reactions and ineffective treatment, investigators shall take corresponding therapeutic measures depending on the subject’s actual conditions.

C. Relevant test data of drop out cases shall be kept properly in archives, and get ready for analysis and statistics. Drop out cases don’t need substitutes.

(V) Reject of cases

1. “Violation of validity” means that case selection violates inclusion standard, and shall not be included in randomization.

2. The subject hasn’t used the experimental drug.

3. There is no data after randomization.

Before data statistics and analysis, statisticians and main investigators discuss and judge whether the case shall be rejected or not.

V. Experimental Drug and Therapeutic Scheme

1. Experimental drug and name

(1) Experimental drug: Qianliekang Brand Pule'an Tablet provided by the sponsor. Specification: 60 tablets/bottle.

(2) Control drug: Proscar (Finasteride Tablets), produced by Hangzhou MSD Pharmaceutical Co. Ltd. Specification: 7 tablets/box.

2. Package of experimental drug

Because this is open experiment, there are no special requirements on the package of experimental drugs.

3. Codes of experimental drug. The sponsor adds consecutive serial numbers to experimental drug. Code of experimental drug is the only identification code of the subjects.

4. Distribution of experimental drug

Experimental drugs shall be distributed according to the coding of experimental center and serial numbers of experimental drug, as well as the number of cases.

Every research unit shall designate one controller of experimental drug. Investigators choose qualified subjects. After the subject signs "Information Consent Form" and investigators write the case history, the controller of experimental drug will distribute drugs according to the treatment sequence of subjects and codes of experimental drugs (otherwise, randomization will be destroyed), and then register in "Use Record of Clinical Trial Medicines".

5. Stocktaking of experimental drugs

During every follow-up visit, investigators shall record the distribution amount of experimental drugs, subjects' intake amount and return amount.

Standard of subjects' intake compliance=(actual intake amount/ prescriptive intake amount) × 100%. If compliance is 80%~120%, the compliance is good.

6. Dosing

Trial group: Pule'an Tablet, oral administration, 4 tablets every time, 3 times per day

Control group: Finasteride Tablet, oral administration, 1 tablet every time, 1 time per day

Time of observation is 90 days. At the 45th day, give symptom scores and don’t carry out laboratorial examination. At the 90th day, give symptom scores and carry out laboratorial examination.

VI. Observation Items

(I) General records

Codes of experimental drugs, codes of hospitals, initials of subjects, outpatient/inpatient, date of starting the experiment

(II) Observation indicator

1. Biological indicators

Demographic characteristics: gender, age, height, weight

Vital signs: body temperature, resting heart rate, breath, blood pressure after 10-minute rest (systolic pressure and diastolic pressure) and so on

2. Diagnostic indicators

Symptoms and signs, course of disease, severity extent

Diagnosis indicators of physico-chemical examination: B-ultrasonic examination, measurement of urine flow rate and PSA blood test (carried out when entering the group).

3. Indicator for curative effect

(1) Major indicators for therapeutic effect

International Prostate Symptoms Scores (IPSS) shall be carried out once at the first diagnosis, the 45^{th} day and the 90^{th} day respectively.

Maximum flow rate shall be measured once at the first diagnosis and the 90^{th} day respectively.

(2) Minor indicators for therapeutic effect

The effects of urinary symptom on quality of life, relevant symptoms and signs;

Indicators of physico-chemical examination: measure the size of prostate through B-ultrasonic examination, and thus calculate the weight of prostate. B-ultrasonic examination and measurement of residual urine volume shall be carried out once at the first diagnosis and the 90^{th} day respectively.

(3) Comprehensive therapeutic effect

4. Safety observation

All centers draw 20% cases at random, and carry out safety observation, including:

Blood routine test, stool routine test and urine routine test

Cardiograph, liver function (AST, ALT) and renal function (BUN, Scr)

Adverse events

Safety evaluation

5. Experiment assessment index

Whether it is drop out or not

Compliance

(III)Time point of observation

1. Main symptoms and signs: observe and record main symptoms and signs once respectively at the first day of the first diagnosis, at the 45th and 90th day.

2. All laboratorial examinations of curative effect and safety shall be carried out once respectively before and after treatment (go through liver and renal function test again within 7 days after treatment). If the subject is cured and the treatment is stopped in advance, physico-chemical re-examination may be carried out ahead of schedule.

(IV) Evaluation criteria of therapeutic effect and safety

1. Evaluation criteria of therapeutic effect

(1) Excellent: After treatment, maximum flow rate is improved by ≥3 ml/second, and I-PSS score drops by 60%.

(2) Effective: After treatment, maximum flow rate is improved by ≥3 ml/second, and I-PSS score drops by 30%.

(3) Ineffective: the case doesn’t reach the standard of effectiveness.

2. Evaluation criteria of safety

Level 1: safe, without any adverse reactions.

Level 2: relatively safe. If adverse reactions occur, the subject doesn’t need any handling and can continue to take the medicine.

Level 3: with safety problems and medium adverse reactions. The subject can continue to take the medicine after handling.

Level 4: stop the experiment due to adverse reactions.

3. Criteria of judging the serious extent of adverse events

Mild: the subject is able to bear, and the treatment is not affected. It doesn’t need any special disposal, and the recovery of the subject is not affected.

Medium: the subject finds it difficult to bear, needs to withdraw the medicine and stop the experiment, or make some special disposal. The recovery of the subject is affected directly.

Serious: endanger the subject's life; the subject dies or is disabled. Withdraw the medicine immediately or make some special disposal.

VII. Observation of Adverse Events

1. Observation and Record

The investigator should ask patients to faithfully reflect their condition changes after taking the medicine and should avoid induced questions.

Write down any adverse reaction that occurs during the test in the "Table for Adverse Events", track and research the reaction, and record the process and result of dealing with the reaction till the test shows that the condition is back to normal and symptoms and signs disappear. Tracking modes could be hospitalization, outpatient service, home visit, telephone or communication according to the seriousness of adverse reaction.

2. Medical Treatment

When adverse reaction happens, the investigator, basing on patients' condition, decides the measures of diagnoses and treatments and decides whether the observation should be stopped. When a serious adverse event happens, the unit that assumes the clinical research should take necessary treatment at once to protect subject' safety and at the same time notify the monitor.

3. Report

The investigator fills in the "Report of Serious Adverse Events", respectively reports to Department of Drug Registration of State Drug Administration, Department of Drug Safety and Inspections of State Drug Administration, Provincial Drug Administration, Sponsor and Ethics Committee in 24 hours, and signs and dates the report. The sponsor shall notify the participating institutions in time and make sure that the report procedure complies with relevant laws and statutes.

Emergent situation, including serious adverse reactions, especially the lethal adverse reaction, should be reported to the specialized agency for monitoring adverse drug reactions in the local province, autonomous region or municipality directly under the central government through using the most convenient communication methods (including telephone, fax, express mail service, E-mail and so on).

VIII. Data Management

(I) Medical record for research

As the outpatient medical records in our country are generally held by patients themselves, so “Medical Record for Research” specially used for the clinical trial is designed to integrally save the first-hand data.

“Medical Record for Research” is the original document of clinical subject and should be kept in the hospital. “Medical Record for Research” is the medical record data of outpatient subject and forms the medical record data of hospitalization subject together with hospitalization medical record.

(II) Data Record

1. Requirements for recording the medical record: ①The investigator must write down the medical record when making diagnoses and treatments for the subject and ensure that the data record is timely, complete, exact and true. ②Score the record if correction is needed and use marginal note for the changed data. The investigator makes the signature and marks the data. Original record should not be erased or covered. ③Stick the original assay sheet of the outpatient subject to the Medical Record for Research and stick the original assay sheet of the hospitalization subject to the Hospitalization Medical Record. Assay result of outpatient and hospitalization subject should be filled in the “Physicochemical Examination Result Report” of the Medical Record for Research.

2. Auditing of Medical Record for Research: When the observation treatment period of each subject finishes, the investigator should submit in time the “Medical Record for Research”, “Information Consent Form” and “Patient Dosage Record Card” to the unit’s main investigators for approve and signature. Deal with the problems found and keep a record.

(III) Data Monitoring

Number of monitors and times of visit should meet the quality control requirements of clinical trial. The monitor audits each Medical Record for Research and fills out each “Monitor Approve Page”.

(IV) Data Processing

1. The monitor seals the completed Medical Record for Research, submits it to the chief unit base project principal and conducts the handing over procedures.

2. The data controller examines the Medical Record for Research in accordance with the clinical trial protocol and fills in the Query List if there's any question. The investigator answers in written form the questions in the Query List, makes a signature and returns it to the data controller. The Query List should be properly kept.

The chief unit is responsible for creating database; use "double entry", computer and labor check and lock the database.

IX. Statistical Analysis

1. Statistical Analysis Plan and Statistical Software

1. After the test protocol is fixed, the professional statistician negotiates with main investigators to formulate statistical analysis plan. Use SAS 6.12 statistical software.

2. Selection of Analysis Data Sets

Full Analysis Set: namely, ideal subject set close to intentional analysis principle (the key analysis must includes all subjects) and this data set is gained through elimination which is done among all subjects with the smallest and reasonable method. Estimate the missing value of key variable by carrying the result that is closest to one-time observation forward to the test missing data; number of subject for evaluation of therapeutic efficiency at the end of the test should be equal to that at the beginning.

Per Protocol Set: Accord with testing treatment protocol; major variable can be measured; baseline variable is not missing; no serious violation against the testing protocol.

Security Set: All subjects that receive treatment for at least one time.

Respectively use Full Analysis Set and Per Protocol Set for maximum flow rate and I-PSS score; use Per Protocol Set for demography, other baseline characteristics and therapeutic index analyses.

3. Content of Statistical Analysis

Actual quantity of selected subject in two groups, situation of cases drop out or being eliminated, demography and other baseline characteristics, compliance, therapeutic efficiency analysis and security analysis.

4. Method of Statistical Analysis

Descriptive statistical analysis, qualitative index is expressed by frequency table, percentage or constituent ratio description; qualitative index is expressed by mean, standard deviation, or

median, lower quartile (Q1) and upper quartile (Q3) description.

Make contrastive analysis between the two groups, qualitative data adopts chi-square test, Fisher precise probabilistic method, Wilcoxon rank sum test, CMH^2 test and WLS covariance. t test will be used if qualitative data conforms to normal distribution (doing homogeneity test of variances between groups, takes 0.5 as the test level and makes the proofreading t test with Satterthwaite method when the variance is homogeneous) and Wilcoxon rank sum test, Wilcoxon signed rank sum test and GLM covariance will be used if does not conform to normal distribution; Hypothesis test uses two-sided test in a unified way, presents Test statistic and the corresponding P value and considers $P \leqslant 0.05$ as statistical significance.

X. Ethical Principle

(I) Main investigators and the sponsor agree on the clinical trial protocol and carry out the protocol after the protocol being approved by the ethics committee. If the protocol is emended during the clinical trial, the emended protocol can be carried out only after being approved by the ethics committee. If important new data relating to test medicine is found, modify the Information Consent Form and submit it to the ethics committee for approval and again obtain subject's agreement.

All clinical trial centers agree that under normal circumstances the research project is examined by chief unit's ethics committee and filed by ethics committees of centers. If necessary (for example, serious adverse event occurs), ethics committee of each center should immediately hold a meeting for the examination and notify other ethics committees of the examination conclusion.

(II) Benefit and Risk: Benefit that the subject can get from the clinical trial: The subject will get effective clinical treatment and medication of favorable security, and especially the symptom will be improved by using the test medicine; the subject can also receive medical treatment for free.

Risks that the subject may be confronted with: The test medicine may have side effect or adverse reaction such as gastrointestinal problems. Medical treatment solutions have been formulated for the known side effect or adverse reaction, including that the investigator is entitled to stop the clinical trial on the basis of his or her own judgment.

(III) Recruitment of Subject: Recruit hospital subject and release relevant information by putting up a notice→registration of interested candidates→read research introduction→physical examination of postulants→selection→the eligible sign the Information Consent Form→select

subject→random grouping. Refer to the appendix for the notice and the research introduction and submit them to the ethics committee for examination.

(IV) Medical Treatment and Protection for Subject: Investigators of test centers take charge of the medical treatment for the subject, make decisions relating to clinical trial and make sure that the subject will receive proper treatment when adverse event occurs during the test.

The sponsor should study the serious adverse event with the investigator at once, take necessary measures to ensure the subject's safety and interests, duly report to Drug Safety and Inspections Department and at the same time inform other investigators involved in the clinical trial which uses the same medicine of the adverse event.

Treatment expense and economic compensation due to relevant injury or death of the subject should be borne by the sponsor. The sponsor should provide the investigator with legal and economic guarantee, but not including injury or death caused by medical negligence.

During the clinical trial, the subject will get test medicine and receive physicochemical examination for free; the subject will be compensated for the inconvenience of transportation and examination and loss of working time caused by participation in the clinical trial. The subject will get cost-free treatment if an adverse event concerned with the test medicine occurs.

(V) Subject Privacy Protection: Only investigators participating in the clinical trial and monitors have access to the subject's personal treatment records. "Investigator Statement" and "Promise of Privacy" signed by them stipulate the content that should be kept confidential. The drug safety and inspection department has the right to inspect the clinical trial record. Use "data anonymity" for data processing and omit the personal recognizable information of the subject. Treatment record of subject should be kept in the data file room of the National Base for Drug Clinical Trial.

(VI) Course of Informed Consent: When selecting qualified postulants, the investigator must clearly explain the conditions relating to the clinical trial, including test purpose, test procedure, possible benefit and risk, subject's right and obligation and so forth. The subject gets a full understanding, has enough time for consideration, expresses agreement after all questions brought forward being satisfactorily replied and signs the "Information Consent Form", and then the clinical trial can start. When the patient signs the "Information Consent Form", the doctor should give his or her telephone or cell phone number to the patient, so the patient can get in contact with the doctor when there's any change of illness state.

XI. Statistical Results

CI	Confidence Interval
CMH	Cochran-Mantel-Haenszel Test
F	F-statistic (variance analysis result)
ITT	Intent To Treat
Max	Maximum Value
Min	Minimum Value
PP	Per Protocol
SD	Standard Deviation
01	Beijing Hospital
02	China-Japan Friendship Hospital
03	General Hospital of People's Liberation Army
04	The First Affiliated Hospital of Zhejiang Chinese Medical University
05	Sir Run Run Shaw Hospital Affiliated to School of Medicine, Zhejiang University (All hyperplasia cases are put into General Hospital of China PLA).
06	Guangxing Hospital Affiliated to Zhejiang Chinese Medical University

1. Case analysis

The study has 260 cases in the planned group and 236 cases in the actual group, while the remaining 24 cases are not included in the study. There are 177 cases in medicine group in statistics of curative effects, 2 rejected cases and 175 actually finished cases; there are 59 cases in control group, 1 rejected cases and 58 actually finished cases.

Table 1-1 Case Distribution

	Medicine group N (%)	Control group N (%)	χ^2	P Value	Methods
Aggregate					
Cases in the group	177	59	0.1125	0.7373	
Finished case	175(98.87)	58(93.81)			
Drop out case	0(0.00)	0(0.00)			
Rejected case	2(1.13)	1(1.69)			
Beijing Hospital					
Cases in the group	30	10	-	-	
Finished case	30(100.00)	10(100.00)			
Drop out case	0(0.00)	0(0.00)			
Rejected case	0(0.00)	0(0.00)			
China-Japan Friendship Hospital					

Cases in the group	23	7	0.1863	0.6660	
Finished case	21(91.30)	6(85.71)			
Drop out case	0(0.00)	0(0.00)			
Rejected case	2(8.70)	1(14.29)			
Beijing 301 Hospital					
Cases in the group	63	21	-	-	
Finished case	63(100.00)	21(100.00)			
Drop out case	0(0.00)	0(0.00)			
Rejected case	0(0.00)	0(0.00)			
The First Affiliated Hospital of Zhejiang Chinese Medical University					
Cases in the group	25	9	-	-	
Finished case	25(100.00)	9(100.00)			
Drop out case	0(0.00)	0(0.00)			
Rejected case	0(0.00)	0(0.00)			
Guangxing Hospital of Zhejiang Chinese Medical University					
Cases in the group	36	12	-	-	
Finished case	36(100.00)	12(100.00)			
Drop out case	0(0.00)	0(0.00)			
Rejected case	0(0.00)	0(0.00)			

Table 1-2 Detailed List of Drop out and Rejected Cases

Center	Group	Medicine No.	Reason for Discontinuation	Kind of Discontinuation	Classify
China-Japan Friendship Hospital	Medicine Group	081	False Acceptance	Rejected	SS
China-Japan Friendship Hospital	Medicine Group	087	False Acceptance	Rejected	SS
China-Japan Friendship Hospital	Control Group	082	False Acceptance	Rejected	SS

2. Comparability analysis

Compare general information of all groups before treatment, including marriage status, nature of work, nationality and so on. General information such as height, weight, body temperature, breath and blood pressure are all comparable; I-PSS score, including emiction, is comparable. Such indicators as age and I-PSS score have statistical difference.

Table 2-1 General information

	Medicine group N（%）	Control group N （%）	χ^2	P value	Method
Marriage status					
Married	175（100.00）	58（100.00）	-	-	
Single	0（0.00）	0（0.00）			
Total	175	58			

Nature of work					
Physical labor	7（6.90）	4（6.90）	0.8125	0.3674	
Non-physical labor	168（96.10）	54（93.10）			
Total	175	58			
Nationality					
Han nationality	174（99.43）	58(100.00)	0.3329	0.5640	
Others	1（0.57）	0(0.00)			
Total	175	58			

Table 2-2 Age (years old)

Aggregate	Medicine Group	Control Group	Statistics	P Value	Method
N	175	58			
Mean ± SD	66.10(8.40)	68.33(7.68)			
Min~Max	33.09~80.00	50.00~79.82	3.191	0.0753	
Median	66.48	69.64			

Table 2-2 General Information

Item	Medicine Group	Control Group	Test statistic	P Value
Weight (kg)				
N (Missing)	175	58	0.026(F Value)	0.8710
Mean (SD)	69.04(8.51)	69.25(8.11)		
Min-Max	45.00-95.00	50.00-85.00		
Median	70.00	70.00		
Height (cm)				
N (Missing)	175	58	0.164(F Value)	0.6862
Mean (SD)	170.15(4.72)	170.44(4.56)		
Min-Max	150.00-183.00	160.00-182.00		
Median	170.00	170.00		
Body Temperature				
N (Missing)	175	58	0.396(F Value)	0.5300
Mean (SD)	36.36(2.51)	36.57(0.32)		
Min-Max	3.70-37.20	36.00-37.10		
Median	36.50	36.55		
Breath (times)				
N (Missing)	175	58	0.341(Rank sum)	0.5591
Mean (SD)	18.29(1.17)	18.40(1.14)		
Min-Max	16.00-21.00	16.00-20.00		
Median	18.00	18.00		
Pulse (times)				
N (Missing)	175	58	0.603(Rank sum)	0.4373
Mean (SD)	76.99(11.31)	76.40(7.42)		
Min-Max	50.00-162.00	55.00-88.00		
Median	78.00	75.50		
Diastolic Pressure (mmHg)				

N (Missing)	175	58	0.046(F Value)	0.8301
Mean (SD)	98.42(24.82)	99.22(24.71)		
Min-Max	50.00-145.00	60.00-160.00		
Median	86.00	90.00		
Systolic Pressure (mmHg)				
N (Missing)	175	58		
Mean (SD)	110.69(24.88)	110.81(21.18)		
Min-Max	60.00-160.00	68.00-155.00		
Median	120.00	120.00		

Table 2-3 Course of Disease (month)

Aggregate	Medicine Group	Control Group	Mean Difference	P Value	Method
N	175	58			
Mean ± SD	52.01(46.89)	61.43(59.15)	1.534	0.2168	
Min~Max	3.00-242.00	6.00-247.00			Nemenyi
Median	36.00	38.00			Nemenyi

Table 2-5 Grade of Single Item of I-PSS before Inclusion

		Medicine group N	Control group N	Statistic	P Value
Feel endless urination after emiction in the last 1 month					
	0 point	18	4		
	1 point	19	10		
	2 points	40	17		
	3 points	38	14	1.6907	0.1927
	4 points	39	6		
	5 points	18	6		
	Total	172	57		
Want to pee within 2 hours after emiction in the last 1 month					
	0 point	21	5		
	1 point	28	6		
	2 points	42	19		
	3 points	47	15	0.4698	0.4931
	4 points	24	9		
	5 points	9	3		
	Total	171	57		
Stop and start time after time during emiction in the last 1 month					
	0 point	34	18	2.0830	0.1489
	1 point	38	9		
	2 points	41	14		
	3 points	33	9		
	4 points	18	5		
	5 points	8	2		

	Total	172	57		
Cannot wait to pee in the last 1 month					
	point	44	10		
	point	28	20		
	2 points	50	10		
	3 points	28	7	0.0168	0.8967
	4 points	14	7		
	5 points	7	3		
	Total	171	57		
Feel urinary stream is smaller in the last 1 month					
	0 point	26	6		
	1 point	31	10		
	2 points	50	17		
	3 points	36	14	0.5336	0.4651
	4 points	20	4		
	5 points	9	6		
	Total	172	57		
Feel difficult to pee in the last 1 month					
	0 point	31	15		
	1 point	30	13		
	2 points	49	15		
	3 points	36	6	4.0146	0.0451
	4 points	15	4		
	5 points	11	3		
	Total	172	56		
Times of nocturia in the last 1 month					
	0 point	2	0		
	1 point	13	7		
	2 points	60	19		
	3 points	71	16	0.3403	0.5596
	4 points	20	8		
	5 points	6	7		
	Total	172	57		

Table 2-6 Total I-PSS Score

Aggregate	Medicine group	Control group	Statistic	P value
N	175	58		
Mean±SD	15.44(3.66)	14.95(3.60)	0.794	0.3738
Min~Max	5.00-21.00	8.00-23.00		
Median	16.00	15.00		

Table 2-7 The Effects of Urinary Symptom on Quality of Life

		Medicine group N（%）	Control group N（%）	Statistic	P value
Quality of life index (L)					
	0 point	0	0		
	1 point	2	6		
	2 points	13	10		
	3 points	60	17	0.392	0.4219
	4 points	71	14		
	5 points	20	4		
	6 points	6	6		
	Total	172	57		

Table 2-8 B-ultrasonic Examination

	Medicine group N（%）	Control group N（%）	χ^2	P Value
Volume of prostate				
Normal	0.（0.00）	0（0.00）		
Abnormal	175（100.00）	58（100.00）	-	-
Total	175	58		

Table 2-9 PSA Blood Test (T-PSA＜4 is normal)

	Medicine group N（%）	Control group N（%）	X2	P Value
Blood PSA value				
Normal	172	57		
Abnormal	3	1		
Total	175	58		

This scheme doesn't have specific requirement of the range of PSA blood test, so PSA blood test is included according to range of laboratorial normal value. All clinical hospitals regard 10% higher as the upper limit. During the experiment, 4 PSA abnormal cases exceed the upper limit of normal value by 0.1-0.4 unit. Through comprehensive judgment, clinical doctors eliminate the possibility of prostatic cancer, so these 4 PSA abnormal cases are included in the experiment. After the experiment is finished, re-examination of these cases shows that they are normal.

3. Assessment of Obedience

Except drop out cases, other finished cases have good obedience.

Table 3-1 Assessment of Obedience

Aggregate	Medicine Group N (%)	Control Group N (%)	Statistics	P Value	Method

Bad obedience	0(0.00)	29(50.00)			Fisher (A:B)
Good obedience	175(100.00)	29(50.00)	-	-	Fisher (A:C)
Total	175	58			Fisher (B:C)

Table 3-2 Combined Medication during Experiment

Aggregate	Medicine Group N (%)	Control Group N (%)	Statistics	P Value	Method
Yes	118(67.34)	29(50.00)	-		Fisher (A:B)
No	57(32.57)	29(50.00)	-	--	Fisher (A:C)
Total	175	58	-		Fisher (B:C)

Table 3-3 List of Combined Medication during Experiment

Following medicines have still been taken by patients until they take part in this experiment.

Medicine No.	Center	Initials	Trade Name	Daily Dosage	Reason	Start Date
2	1	WHQZ	Hypotensive No. 0	1 tablet once/day	Hypertension	2000-2-6
4	2	ZXSH	Compound Danshen Dripping Pills	10ml	Coronary heart disease	1990-6-20
6	1	MXFE	Dimethyldiguanide	1 tablet, twice/day	Diabetes	2004-6-20
11	1	LYPI	Norvasc	1 tablet, once/day	Hypertension	2005-6-10
12	2	LSCO	Acarbose	once/day	Diabetes	2003-2-2
21	2	CBPI	Ginkgo Biloba Tablets	2 tablets every time, 3 times/day	Coronary heart disease	2006-11-6
27	2	CCFA	Metoprolol	50mg	Hypertension	2000-9-12
32	2	YXSE	Lotensin	1 tablet/day	Hypertension	2001-4-16
35	1	LZPI	Lotensin	1 tablet/day	Hypertension	1998-12-18
36	1	ZWSU	Norvasc	2 tablets/day	Hypertension	2000-4-5
40	1	GXZH	Extended Release Nifedipine Tablets	1 tablet/day	Hypertension	2006-7-2
43	1	ZZXI	Nifedipine Controlled Release Tablets	10mg once/day	Hypertension	2004-5-20
45	1	LXTI	Isosorbide Mononitrate Tablets	1 tablet, once/day	Coronary heart disease	2005-8-16
46	2	WSDE	Metoprolol	12.5mg, twice/day	Hypertension	1999-10-12
56	1	GJRU	Nifedipine Controlled Release Tablets	10ml, twice/day	Hypertension	2006-4-8
68	2	WGKU	Dimethyldiguanide	1 tablet, once/day	Diabetes	2005-7-8
70	2	LMYA	Metoprolol	2.5mg twice/day	Hypertension	2006-5-16
76	1	PYQI	Levamlodipine Besylate Tablets	1 tablet, once/day	Hypertension	2006-8-16
80	2	HGSH	Lunan Isosorbide Mononitrate Tablets	2 tablets, twice/day	Coronary heart disease	2003-1-18
170	1	WCXZ	Indapamide	1 tablet every time, twice/day	Hypertension	1990-10-18
171	2	EPZH	Metoprolol	1 tablet every time, 3 times/day	Hypertension	2000-7-12
172	1	RYGU	Nifedipine Controlled Release Tablets	1 tablet every time, once/day	Hypertension	2005-12-10

				10 tablets every time, once/day		
173	1	FWXI	Compound Danshen Dripping Pills		Coronary heart disease	2005-7-20
174	2	ZHPE	Xueshuangtong		Cerebral infarction	2006-12-1
175	1	MHLZ	Compound Danshen Dripping Pills	1 tablet every time, twice/day	Coronary heart disease	1998-11-26
176	1	SHLA	Nifedipine Controlled Release Tablets	1 tablet every time, once/day	Hypertension	2006-5-18
177	1	CGZH	Calculus Discharging Granules (Paishi Keli)	2 bags every time, twice/day	Nephrolith	2006-12-2
178	1	WQYU	Levamlodipine Besylate Tablets	1 tablet every time/day	Hypertension	2006-1-16
178	1	WQYU	Levamlodipine Besylate Tablets	1 tablet every time/day	Hypertension	2006-1-16
184	1	HZLO	Nifedipine Controlled Release Tablets	1 tablet every time, once/day	Hypertension	1997-10-18
186	1	HGXU	Nifedipine Controlled Release Tablets	1 tablet every time, twice/day	Hypertension	2006-2-10
189	1	YUFE	Lotensin	1 tablet every time, once/day	Hypertension	1998-11-6
191	1	DSXI	Nifedipine Controlled Release Tablets	1 tablet every time/day	Hypertension	1991-7-18
192	1	LMFA	Isosorbide dinitrate	1 tablet every time/day	Hypertension	2006-3-12
195	1	ZWXU	Metoprolol	1 tablet every time, 3 days/time	Hypertension	1998-9-6
197	2	LRLI	Levamlodipine Besylate Tablets	2 tablets every time, twice/day	Hypertension	2006-1-12
198	1	YUFE	Levamlodipine Besylate Tablets	1 tablet every time, once/day	Hypertension	2001-3-18
201	1	LGYU	Levamlodipine Besylate Tablets	1 tablet every time, once/day	Hypertension	2006-1-12
202	1	ZZRU	Nifedipine Controlled Release Tablets	1 tablet every time, once/day	Hypertension	2003-2-21
204	1	YYZH	Nifedipine Controlled Release Tablets	1 tablet every time, twice/day	Hypertension	1997-11-20
205	2	ZZRU	Xinkang	1 tablet every time, 3 times/day	Coronary heart disease	2003-9-8
206	1	WJKU	Levamlodipine Besylate Tablets	1 tablet every time, twice/day	Hypertension	2005-1-3
207	1	WLWE	Nifedipine Controlled Release Tablets	1 tablet every time, once/day	Hypertension	2000-9-12
211	2	WNZH	Xinkang	2 tablets every time, once/day	Angina pectoris	1997-2-16
216	1	WYCH	Beijing Hypotensive No. 0	5mg	Hypertension	2002-3-1
232	1	HJGE	Captopril	12.5mg	Hypertension	1994-10-1

4. Analysis of therapeutic effect

4.1 Therapeutic effect on I-PSS score

Analysis of I-PSS therapeutic effect: Total effective rate of medicine group is 85.14% (n=175), and total effective rate of control group is 86.21% (n=58). The comparison between medicine group and control group has no statistical significance. Medicine group and control group have basically the same therapeutic effects. There are no differences among all centers. Markedly effective rate of medicine group is 37.14% (n=175), and markedly effectively rate of control group is 51.72% (n=58). In this aspect, control group is better than medicine group, which has remarkable difference.

Table 4-1 Judgment and Analysis of I-PSS Therapeutic Effects among All Centers

	N	Excellent	Effective	Ineffective	Total markedly effective rate %	Total effective rate
Aggregate						
Medicine group	175	65	84	26	37.14	85.14
Control group	58	30	20	8	51.72	86.21
Center 1						
Medicine group	30	15	10	5	50.00	83.33
Control group	10	5	3	2	50.00	80.00
Center 2						
Medicine group	21	6	11	4	28.57	80.95
Control group	6	5	1	0	83.33	100.00
Center 3						
Medicine group	63	27	25	8	42.86	82.54
Control group	21	11	8	2	52.38	90.48
Center 4						
Medicine group	25	6	16	3	24.00	88.00
Control group	9	2	5	2	22.00	77.78
Center 5						
Medicine group	36	8	22	6	22.22	83.33
Control group	12	7	3	2	58.33	83.33
Note: Total excellent rate=excellent effective cases/total cases×100%; Total effective rate= (excellent effective cases +effective cases) /total cases×100%.						

4.2 Analysis of I-PSS score

4.2.1 Analysis of I-PSS score changes

Analysis of I-PSS score changes: medicine group drops by 8.06 (n=174)；Control group drops by 7.76 (n=58). There is no marked difference between these two.

Table 4-2 Analysis of I-PSS Score (take medicine for 90d) and Pre-treatment Changed Value (after-before)

Item	Medicine group	Control group	Test Statistic	P Value
IPSS total score difference				
N	175	58	0.215 (F value)	0.6431
Mean(SD)	-8.06（4.00）	-7.76（4.93）		
Min-Max	-19.00-2.00	-19.00-1.00		
Median	-7.00	-6.00		

4.2.2 Diachronic analysis of I-PSS score changes

Table 4-4 Diachronic Changes of Measured Value of I-PSS Score (comparison between groups and before-and-after analysis in the same group)

Item	Medicine group	Control group	Test Statistic	P Value
I-PSS total score-the 0 day				
N	175	58	0.691 (F value)	0.4066
Mean(SD)	15.57(3.87)	15.09(3.80)		
Min-Max	5.00-28.00	8.00-23.00		
Median	16.00	15.00		
I-PSS total score-the 45th day				
N	175	58	0.591 (F value)	0.6958
Mean(SD)	11.13(3.62)	11.59（4.17）		
Min-Max	2.00-20.00	3.00-18.00		
Median	12.00	10.00		
Pairing t (P)	17.29(＜0.0001)	9.78(＜0.0001)		
I-PSS total score-the 90th day				
N	174	58		
Mean(SD)	7.55(3.64)	7.33（4.15）		
Min-Max	1.00-18.00	2.00-16.00		
Median	8.00	7.00		
Pairing t (P)	26.59(＜0.0001)	11.98(＜0.0001)		

Table 4-5 IPSS Total Score Difference

Item	Medicine group	Control group	Test Statistic	P Value
I-PSS total score difference (the 45th day-0 day)				
N	175	58	1.372(F value)	0.2676
Mean(SD)	-4.48（3.42）	-3.50（4.28）		
Min-Max	-15.00-4.00	-16.00-2.00		
Median	-4.00	-4.00		
I-PSS total score difference (the 90th day-0 day)				
N	175	58	0.215(F value)	0.6431
Mean(SD)	-8.06（4.00）	-7.76（4.93）		
Min-Max	-19.00-2.00	-19.00-1.00		
Median	-7.00	-6.00		

Comparison of I-PSS total score difference shows that there is no obvious difference between medicine group and control group.

4.3 Test and analysis of maximum flow rate

Table 4-6 Difference of Maximum Flow Rate

Item	Medicine group	Control group	Test Statistic	P Value
Difference of maximum flow rate (ml)				
N	175	58	5.579 (F value)	0.0190
Mean(SD)	5.13(5.28)	3.32(4.20)		
Min-Max	-4.60-26.60	-6.00-18.70		
Median	4.00	3.00		

5. Analysis of volume changes of prostate

Table 5-1 Comparison of the Volume of Prostate before and after Treatment

Group	Total case	Before treatment (cm^3)	After treatment (cm^3)	T	P
Test group	175	43.12±12.68	39.45±19.83	1.67	＞0.05
Control group	58	39.78±12.94	40.36±12.71	-0.66	＞0.05

After Test Group takes Qianliekang Pule'an Tablet for 90 days, the volume of their prostate decreases, but only decreases a little. There is no obvious difference before treatment and after treatment. As for Control Group, the volume of their prostate almost has no change before treatment and after treatment.

6. Analysis of changes of residual urine volume

Table 6-1 Comparison of Residual Urine Volume before and after Treatment

Group	Before treatment		After treatment		X^2	P
	Normal case	Abnormal case	Normal case	Abnormal case		
Test group	145	25	162	8	9.70	＜0.01
Control group	47	11	53	5	5.20	＜0.05

7. Safety Analysis

7.1 Laboratory examination

Table 7-1 Overall List of Safety Index Normal/Abnormal and Abnormal/Abnormal before and after Treatment

	N (Deletion)	Normal/ Normal	Normal/Abnormal (Rate of abnormality %)	Abnormal/ Normal	Abnormal/ Abnormal
WBC					

	Medicine group	48	46(95.83）	0(0.00)	1(2.08)	1(2.08)
	Control group	14	12(85.71）	0(0.00)	1(7.14)	1(7.14)
RBC						
	Medicine group	48	46(95.83）	0(0.00)	2(4.16)	0(0.00)
	Control group	14	14(100.00）	0(0.00)	0(0.00)	0(0.00)
HB						
	Medicine group	48	45(93.75）	0(0.00)	2(4.17)	1(2.08）
	Control group	14	14(100.00）	0(0.00)	0(0.00)	0(0.00）
PLT						
	Medicine group	48	48(100.00)	0(0.00)	0(0.00)	0(0.00）
	Control group	14	12(85.71)	0(0.00)	2(14.29)	0(0.00）
Urine WBC						
	Medicine group	48	44(91.67)	0(0.00)	4(8.33)	0(0.00)
	Control group	14	12(85.71)	0(0.00)	1(7.14)	1(7.14)
Urine RBC						
	Medicine group	48	47(97.92)	0(0.00)	1(2.08)	0(0.00)
	Control group	14	13(92.86)	0(0.00)	1(7.14)	0(0.00)
Urine protein						
	Medicine group	48	43(89.58)	0(0.00)	5(10.42)	0(0.00)
	Control group	14	13(92.86)	0(0.00)	1(7.14)	0(0.00)
ALT						
	Medicine group	48	18(100.00）	0(0.00)	0(0.00)	0(0.00）
	Control group	14	14(100.00）	0(0.00)	0(0.00)	0(0.00）
AST						
	Medicine group	48	18(100.00）	0(0.00)	0(0.00)	0(0.00)
	Control group	14	14(100.00）	0(0.00)	0(0.00)	0(0.00)
BUN						
	Medicine group	48	44(91.67)	0(0.00)	3(6.25)	1(2.08)
	Control group	14	14(100.000	0(0.00)	0(0.00)	0(0.00)
CR						
	Medicine group	48	48(100.00)	0(0.00)	0(0.00)	0(0.00)
	Control group	14	14(100.00)	0(0.00)	0(0.00)	0(0.00)
Cardiogram						
	Medicine group	48	33(68.75)	0(0.00)	5(10.42)	10(20.83)
	Control group	14	9(64.29)	0(0.00)	3(21.43)	2(14.29)

Table 7-2 List of Abnormal Values of WBC Determination before Treatment (before taking medicine) and after Treatment (take medicine for 90d)

Center	Medicine No.	Group	Value before medicine ($\times 10^9$/L)	Judgment before medicine	Value after medicine ($\times 10^9$/L)	Judgment after medicine	Note
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	226	Medicine group	3.3	Abnormal	6.2	Normal	-

Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	241	Medicine group	2.9	Abnormal	2.9	Abnormal	-
China-Japan Friendship Hospital	85	Control group	3.9	Abnormal	5.05	Normal	-
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	215	Control group	3.3	Abnormal	3.6	Abnormal	-

Table 7-3 List of Abnormal Values of RBC Determination before Treatment (before taking medicine) and after Treatment (take medicine for 90d)

Center	Medicine No.	Group	Value before medicine ($\times10^9$/L)	Judgment before medicine	Value after medicine ($\times10^9$/L)	Judgment after medicine	Note
The First Affiliated Hospital of Zhejiang Chinese Medical University	133	Medicine group	3.76	Abnormal	-	-	Not do
The First Affiliated Hospital of Zhejiang Chinese Medical University	147	Medicine group	5.67	Abnormal	4.88	Normal	

Table 7-4 List of Abnormal Values of HB Determination before Treatment (before taking medicine) and after Treatment (take medicine for 90d)

Center	Medicine No.	Group	Value before medicine (g/L)	Judgment before medicine	Value after medicine (g/L)	Judgment after medicine	Note
Beijing Hospital	10	Medicine group	180	Abnormal	174.1	Abnormal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	134	Medicine group	161	Abnormal	154	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	147	Medicine group	179	Abnormal	167	Normal	-

Table 7-5 List of abnormal values of PLT determination before treatment (before taking medicine)

and after treatment (take medicine for 90d)

Center	Medicine No.	Group	Value before medicine ($\times 10^9$/L)	Judgment before medicine	Value after medicine ($\times 10^9$/L)	Judgment after medicine	Note
Beijing Hospital	4	Control group	317	Abnormal	203	Normal	-
Beijing 301 Hospital	70	Control group	327	Abnormal	175	Normal	-

Table 7-6 List of abnormal values of Urine WBC determination before treatment (before taking medicine) and after treatment (take medicine for 90d)

Center	Medicine No.	Group	Value before medicine	Judgment before medicine	Value after medicine	Judgment after medicine	Note
Beijing Hospital	4	Control group	1~2	Abnormal	1~2	Abnormal	Stomatitis infection
Beijing Hospital	6	Medicine group	2	Abnormal	0	Abnormal	Recheck normal
Beijing Hospital	8	Medicine group	2	Abnormal	0	Normal	Recheck normal
The First Affiliated Hospital of Zhejiang Chinese Medical University	130	Medicine group	1~2	Abnormal	0	Normal	Recheck normal
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	219	Medicine group	2	Abnormal	0	Normal	Recheck normal
China-Japan Friendship Hospital	252	Medicine group	1~2	Abnormal	0	Normal	Recheck normal

Table 7-7 List of abnormal values of Urine RBC determination before treatment (before taking medicine) and after treatment (take medicine for 90d)

Center	Medicine No.	Group	Value before medicine	Judgment before medicine	Value after medicine	Judgment after medicine	Note
Beijing Hospital	4	Control group	1~2	Abnormal	0	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	126	Medicine group	1~2	Abnormal	0	Normal	-

Table 7-8 List of abnormal values of Urine Protein determination before treatment (before taking medicine) and after treatment (take medicine for 90d)

Center	Medicine	Group	Value	Judgment	Value	Judgment	Note

	No.		before medicine	before medicine	after medicine	after medicine	
Beijing Hospital	6	Medicine group	Minim	Abnormal	0	Normal	Recheck normal
Beijing Hospital	8	Medicine group	Minim	Abnormal	0	Normal	Recheck normal
China-Japan Friendship Hospital	130	Medicine group	Minim	Abnormal	0	Normal	Recheck normal
The First Affiliated Hospital of Zhejiang Chinese Medical University	219	Medicine group	Minim	Abnormal	0	Normal	Recheck normal
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	252	Control group	Minim	Abnormal	0	Normal	Recheck normal
Beijing Hospital	4	Control group	Minim	Abnormal	0	Normal	Recheck normal

Table 7-9 List of abnormal values of BUN determination before treatment (before taking medicine) and after treatment (take medicine for 90d)

Center	Medicine No.	Group	Value before medicine (mmol/L)	Judgment before medicine	Value after medicine (mmol/L)	Judgment after medicine	Note
Beijing Hospital	2	Medicine group	7.30	Abnormal	7.42	Abnormal	Effect of diet
China-Japan Friendship Hospital	45	Medicine group	7.96	Abnormal	6.45	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	140	Medicine group	7.50	Abnormal	6.55	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	141	Medicine group	8.30	Abnormal	6.81	Normal	-

Table 7-10 List of Abnormal Values of Cardiogram before Treatment (before taking medicine) and after Treatment (taking medicine for 90d)

Center	Medicine number	Group	Value before medicine	Judgment before medicine	Value after medicine	Judgment after medicine	Note
Beijing Hospital	1	Medicine group	Left anterior bifurcation	Abnormal	-	Normal	-
Beijing Hospital	3	Medicine group	Super-voltage in left ventricle	Abnormal	-	Normal	-
Beijing Hospital	8	Medicine group	Nonspecific ST change sinus	Abnormal	-	Normal	-

			rhythm				
Beijing 301 Hospital	47	Medicine group	Atria and ventricular pacing cardiogram	Abnormal	Atria and ventricular pacing cardiogram	Abnormal	Approximately normal
Beijing 301 Hospital	65	Medicine group	Abnormal cardiogram ST	Abnormal	Abnormal cardiogram ST	Abnormal	The same as pretreatment
China-Japan Friendship Hospital	85	Control group	Slight change in ST-T wave	Abnormal	Slight change in ST-T wave	Abnormal	The same as pretreatment
The First Affiliated Hospital of Zhejiang Chinese Medical University	123	Control group	Mild change in T wave	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	129	Control group	Bradycardia, super-voltage in left ventricle	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	132	Medicine group	Bradycardia	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	134	Medicine group	Moderate left deviation of electrical axis	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	136	Medicine group	Sinus bradycardia	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	137	Medicine group	I0 Atrioventricular heart-block	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	140	Medicine group	Moderate left deviation of electrical axis	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	141	Medicine group	Mildly prolonged P-R interval	Abnormal	-	Normal	-
The First Affiliated Hospital of Zhejiang Chinese Medical University	142	Medicine group	Moderate left deviation of electrical axis	Abnormal	Moderate left deviation of electrical axis	Abnormal	The same as pretreatment
The First Affiliated Hospital of Zhejiang Chinese Medical University	143	Medicine group	Sinus bradycardia	Abnormal	-	Normal	
The First Affiliated Hospital of Zhejiang Chinese Medical University	154	Medicine group	T wave change	Abnormal	-	Normal	
The First Affiliated Hospital of Zhejiang Chinese Medical University	173	Medicine group	Complete right bundle branch block, left anterior hemiblock	Abnormal	Complete right bundle branch block	Abnormal	The same as pretreatment
The First Affiliated Hospital of Zhejiang Chinese Medical University	217	Control group	Complete right bundle branch block, sinus	Abnormal	Sinus bradycardia, atrioventricular heart-block	Abnormal	The same as pretreatment

			bradycardia				
Beijing 301 Hospital	221	Medicine group	Bradycardia, left deviation of electrical axis, left anterior hemiblock	Abnormal	Sinus bradycardia, atrioventricular heart-block	Abnormal	The same as pretreatment
Beijing 301 Hospital	223	Medicine group	Block, grade 1 atrioventricular heart-block	Abnormal	Sinus rhythm, left anterior hemiblock, grade 1 atrioventricular heart-block	Abnormal	The same as pretreatment
Beijing 301 Hospital	224	Control group	Slightly right deviation of electrical axis	Abnormal	-	Normal	-
Beijing 301 Hospital	233	Medicine group	Mild change in T wave	Abnormal	-	Normal	-
Beijing 301 Hospital	237	Medicine group	Change in T wave	Abnormal	-	Normal	-
Beijing 301 Hospital	242	Medicine group	R wave abnormal	Abnormal	-	Normal	-
Beijing 301 Hospital	249	Control group	Incomplete right bundle branch block	Abnormal	-	Normal	-
Beijing 301 Hospital	250	Medicine group	Mild change of ST segment	Abnormal	-	Normal	-
Guangxing Hospital Affiliated to Zhejiang Chinese Medical University	251	Medicine group	Mild block of ST segment	Abnormal		Abnormal	The same as pretreatment
Beijing 301 Hospital	257	Medicine group	Change in ST-T	Abnormal		Abnormal	The same as pretreatment
Beijing 301 Hospital	260	Medicine group	Ventricular premature beat, mild change of T wave	Abnormal		Abnormal	The same as pretreatment

Detailed list of normal/abnormal and abnormal/abnormal cases shall be separated.

Table 7-11 Comparison of Liver Function and Renal Function of Some Cases in Test Group before and after Treatment

Item	Case Number	Unit	Before treatment $\chi \pm S$	After treatment $\chi \pm S$	t	p
ALT	62	U/L	21.71±7.48	22.41±6.73	-0.87	0.3898
AST	62	U/L	23.97±6.17	22.49±5.58	1.86	0.0681
Cr	62	umol/L	74.27±11.99	73.91±14.65	0.23	0.8156
BuN	61	umol/L	5.50±1.19	5.58±1.02	-0.58	0.5648

7.2 Adverse Event

No adverse event happens in medicine group and control group.

XII. Statistical Results

1. Case distribution

This study has 260 cases in the planned group and 236 cases in the actual group, while the remaining 24 cases are not included in the study.

Medicine group has 177 cases, 2 rejected cases, and 175 actually finished cases; control group has 59 cases, 1 rejected case, and 58 actually finished cases.

2. Comparability analysis

Compare general information of all groups before treatment, including marriage status, nature of work, nationality and so on. General examination such as height, weight, body temperature, breath and blood pressure are all comparable; I-PSS score and other indicators have statistical difference. (P＜0.050)

3. Analysis of compliance

Except exfoliated cases, other finished cases have good compliance.

4. Analysis of therapeutic effects

4.1 I-PSS therapeutic effects

PP Analysis of I-PSS therapeutic effects: Total effective rate of medicine group is 85.14% (n=175), and total effective rate of control group is 86.21% (n=58). The comparison between medicine group and control group has no statistical significance (P＞0.05). Medicine group and control group have basically the same therapeutic effects.

4.2 Analysis of I-PSS score

4.2.1 Analysis of I-PSS score changes among all centers

Analysis of I-PSS score: medicine group drops by 8.06 (n=175); Control group drops by 7.76 (n=58). The comparison between medicine group and control group has no statistical difference (P＞0.05).

4.2.2 Analysis of change rate of I-PSS scores of all centers

PP Analysis of I-PSS scores: medicine group drops by 4.01% (n=175)； Control group drops by 4.23% (n=58). The comparison between medicine group and control group has no statistical difference (P＞0.05).

4.3 Analysis of changes of maximum flow rate

Maximum flow rates of medicine group and control group before and after treatment have been

enhanced with different degrees. Test group is better than control group (P＜0.05).

4.4 Analysis of volume changes of prostate

After treated by Qianliekang, average value of the volume of prostate decreases; after treated by Finasteride, the volume of prostate doesn't change remarkably. The comparison between test group and control group has no significant difference (P＞0.05).

4.5 Analysis of changes of residual urine volume

Compared with that before treatment, changes of residual urine volume between groups and in the groups after treatment have significant differences, both in test group and control group. However, before treatment, there is no significant difference between them.

5. Safety analysis

No adverse event happens in medicine group and control group.

XIII. Conclusion

Clinical trials of Pule'an Tablet and Proscar show that it is safe and effective to treat prostatitis with Pule'an Tablet. The comparison between the curative effect of medicine group and that of control group doesn't have statistical significance, and curative effect of medicine group is basically identical with that of control group. Both have certain curative effect on improving typical symptoms of prostatitis. Moreover, their differences don't have statistical significance, which means that both curative effects are basically identical. There aren't severe adverse reactions in the experiment. Abnormality in blood and urine routine tests and tests of liver and renal function has been examined again, or given reasonable explanations.

Experimental results show that the curative effect and safety of Pule'an Tablet is reliable in treating prostatitis. This conclusion coincides with application reality of this product. This experiment verifies above viewpoint with normative clinical observations.