Study Identification

Unique Protocol ID: Sanjin tablets

Brief Title: Clinical Study of Sanjin Tablets for the Treatment of Acute Simple Lower Urinary Tract Infection

Official Title: Sanjin Tablets for the Treatment of Acute Simple Lower Urinary Tract Infection and Its Influence on Recurrence Rate: a Randomized, Double Blind, Parallel Control of Positive Drugs, Multi-center Clinical Study

Secondary IDs:

Study Status

Record Verification: November 2018

Overall Status: Not yet recruiting

Study Start: January 1, 2019 [Anticipated]

Primary Completion: June 30, 2019 [Anticipated]

Study Completion: December 31, 2019 [Anticipated]

Sponsor/Collaborators

Sponsor: China Academy of Chinese Medical Sciences

Responsible Party: Principal Investigator

Investigator: Yanming Xie [yanmingxie]

Official Title: Deputy director

Affiliation: China Academy of Chinese Medical Sciences

Collaborators: Xiuyuan Hospital of China Academy of Chinese Medical Sciences

Longhua Hospital Shanghai University of Traditional Chinese Medicine

Guangdong Provincial Hospital of Traditional Chinese Medicine

Hubei Hospital of Traditional Chinese Medicine

Chengdu University of Traditional Chinese Medicine

Yunnan Provinical Hospital of Traditional Chinese Medicine

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: 2018XLA03l-3
Study Description

Brief Summary: The purpose of this study is to evaluate the efficacy, safety and immune mechanism of Sanjin tablets for the treatment of acute simple lower urinary tract infection and its influence on recurrence rate.

Detailed Description: In order to evaluating the efficacy, safety and immune mechanism of Sanjin tablets for the treatment of acute simple lower urinary tract infection and its influence on recurrence rate and through research data to guide clinical, improving the rational use of drugs, especially the rational application of antibiotics. In this study, a randomized, double blind, parallel control of positive drugs, multi-center clinical study will be established. According to the relevant regulations of the CFDA, 252 cases need to be registered at least. These cases will be divided into treatment group (Sanjin tablets+ levofloxacin simulants), control group 1 (Sanjin tablets simulants +levofloxacin) and control group 2 (Sanjin tablets+ levofloxacin). Each group will be treated for 7 days and followed up for 2 times. The efficacy indicators of this study were mainly from three dimensions: syndrome, laboratory routine examination and bacteriology examination. The symptom scores and cytokine changes of each group before and after treatment were observed.

Conditions

Conditions: Urinary Tract Infection Lower Acute
Keywords: Sanjin tablets
efficacy and safety
recurrence rate
randomized
double blind
parallel control
multi-center clinical study

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 4
Interventional Study Model: Parallel Assignment
Number of Arms: 3
Masking: Double (Participant, Investigator)
### Arms and Interventions

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Experimental: Sanjin tablets group</strong></td>
<td>Drug: Sanjin tablets</td>
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<tr>
<td>Sanjin tablets+ levofloxacin simulants</td>
<td>Sanjin tablets, 3 pills/time, 4 times/day, for 7 days</td>
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<tr>
<td></td>
<td>+ levofloxacin simulants, 0.1g, po bid, for 7 days.</td>
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<tr>
<td></td>
<td>Other Names:</td>
</tr>
<tr>
<td></td>
<td>• levofloxacin simulants</td>
</tr>
<tr>
<td><strong>Placebo Comparator: Levofloxacin group</strong></td>
<td>Drug: Sanjin tablets simulants</td>
</tr>
<tr>
<td>Sanjin tablets simulants + levofloxacin</td>
<td>levofloxacin, 0.1g, po bid, for 7 days + Sanjin tablets simulants, 3 pills/time, 4 times/day, for 7 days.</td>
</tr>
<tr>
<td></td>
<td>Other Names:</td>
</tr>
<tr>
<td></td>
<td>• Levofloxacin</td>
</tr>
<tr>
<td><strong>Active Comparator: Sanjin tablets + Levofloxacin group</strong></td>
<td>Drug: Levofloxacin</td>
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<td>Other Names:</td>
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<td>• Sanjin tablets</td>
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### Outcome Measures

**Primary Outcome Measure:**

1. The lower urinary tract infection symptoms of 252 participants will be assessed.
   - The symptoms mainly include frequent urination, urgent urination, urinary pain, lower abdominal pain, and pain in the kidney area. If these symptoms disappear after 7 days of medication, it indicates the subject is cured.
   - **[Time Frame: After 7 days of medication]**

**Secondary Outcome Measure:**

2. The urine leukocyte of 252 participants will be assessed.
   - If the urine leukocyte returns to normal value after 7 days of medication, it indicates the subject is cured.
   - **[Time Frame: After 7 days of medication]**

3. The bacteriological examination of 252 participants.
   - If the original infected part of the specimen did not regenerate the original infected pathogen after 7 days of medication, it indicates the subject is cured.
   - **[Time Frame: After 7 days of medication]**

4. The recurrence rate of subjects who is cured in 252 participants will be assessed by lower urinary tract infection symptoms.
   - If the lower urinary tract infection symptoms of subjects who is cured appears again in the fourth week after end of medication, it indicates the subject has relapsed.
   - **[Time Frame: 28 days after the end of treatment]**

5. The recurrence rate of subjects who is cured in 252 participants will be assessed by urine leukocyte.
   - If the urine leukocyte value of subjects who is cured rises again in the fourth week after end of medication, it indicates the subject has relapsed.
   - **[Time Frame: 28 days after the end of treatment]**

6. The recurrence rate of subjects who is cured in 252 participants will be assessed by bacteriological examination.
If the urine culture of subjects who is cured indicates that the original urinary tract pathogen is positive again in the fourth week after end of medication, it indicates the subject has relapsed.

[Time Frame: 28 days after the end of treatment]

Eligibility

Minimum Age: 18 Years  
Maximum Age: 50 Years  
Sex: All  
Gender Based:  
Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Subjects aged 18 to 50 years of age.  
2. Meets the western diagnostic criteria of acute simple lower urinary tract infection, the disease duration does not exceed 72 hours.  
3. Urine retention in the screening period -1-0 days, bacterial culture results were sensitive to levofloxacin.(Urine retention for bacterial culture and clinical treatment at the same time)  
4. The syndrome differentiation of TCM is syndrome of dampness-heat in lower jiao.  
5. Did not receive antibiotic treatment within 48 hours Before being selected.  
6. The inclusion of those who confirmed not pregnant  
7. Those who agree to participate in this clinical trial and sign the informed consent, the process of informed consent meet the relevant provisions of the GCP.

Exclusion Criteria:

1. Those who are allergic to the test drug ingredients or quinolones.  
2. In the past, there was a history of bacterial culture that was not sensitive to levofloxacin.  
3. Diagnosed as complicated urinary tract infection.  
4. Patients with urinary calculi or obstruction, urinary tuberculosis, renal papillary necrosis, perinephric abscess or neurogenic bladder.  
5. Combined with vaginitis symptoms, genital ulcers or gonorrhea.  
6. Combined with severe cardiopulmonary disease, liver and kidney disease, advanced tumor, blood, central nervous system (such as the history of epilepsy) or other serious or progressive disease.  
7. A patient who has a neurological or mental illness and cannot cooperate.  
8. Infected persons who must use other antibacterial drugs in combination.  
9. Pregnancy, lactating women or recent birth planners.  
10. Those who have participated in other clinical trials within 3 months before being selected.

Contacts/Locations

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Study Officials: Yanming Xie, BA
Study Principal Investigator
Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences

Locations:

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information: