

A study on the efficacy and safety of Ruyi Zhenbao tablets for patients with lumbar disc herniation

Submission date 22/08/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/08/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A lumbar disc herniation is a spinal condition where part of a disc in the lower back pushes out and presses on nearby nerves. This can cause symptoms like lower back pain, pain that radiates down the legs, and numbness in the legs. This condition commonly affects middle-aged and elderly people. However, its incidence is also increasing among younger populations due to poor lifestyle and work habits. Effective and safe treatment options are crucial to improving patients' quality of life.

This research falls within the fields of orthopedics and pain management, with a specific focus on evaluating the effectiveness and safety of the Tibetan medicine Ruyi Zhenbao tablets in treating lumbar disc herniation. This study aims to compare the outcomes of Ruyi Zhenbao tablets with those of the standard treatment, providing evidence-based support for the broader clinical application of Ruyi Zhenbao tablets.

Who can participate?

Patients aged 18-65 years with lumbar disc herniation

What does the study involve?

Participants will be randomly assigned to two groups (the treatment group and the positive control group). Patients in the treatment group will receive Ruyi Zhenbao tablets, while those in the control group will receive a positive control medicine. When the pain score is high, additional treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs), diuretics, and/or corticosteroids will be administered. The study will evaluate lumbar joint dysfunction, the severity of lower back and leg pain, numbness, the proportion of participants in each group requiring rescue therapy, and adherence to health education. The effectiveness of treatment will be assessed in both groups, with all patients undergoing a 4-week treatment period followed by a 4-week follow-up.

What are the possible benefits and risks of participating?

The possible benefits of this study include improvement in lumbar spinal joint dysfunction and relief of lower back and leg pain and numbness. The possible risks include nausea, vomiting, acid

reflux, heartburn, abdominal bloating, diarrhoea, headache, dizziness, rash, skin itching, and erythema (skin redness).

Where is the study run from?

Beijing University of Chinese Medicine (China) (management institution - please see study participating centres for a full list of centres)

When is the study starting and how long is it expected to run for?

July 2024 to December 2026

Who is funding the study?

Tibet Cheezheng Tibetan Medicine Co., Ltd. (China)

Who is the main contact?

1. Prof. Jianping Liu, liujp@bucm.edu.cn

2. Prof. Weishi Li, weishi_li@aliyun.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Jian-Ping Liu

ORCID ID

<https://orcid.org/0000-0002-0320-061X>

Contact details

Centre for Evidence-based Chinese Medicine

Beijing University of Chinese Medicine

11 Bei San Huan Dong Lu

Chaoyang District

Beijing

China

100029

+86 (0)10 64286760

liujp@bucm.edu.cn

Type(s)

Scientific

Contact name

Prof WeiShi Li

Contact details

Peking University Third Hospital

No. 49, Huayuan North Road

Haidian District

Beijing

China

100191
+86 (0)13501358705
weishi_li@aliyun.com

Additional identifiers

Protocol serial number
20240722V2.0

Study information

Scientific Title

Efficacy and safety of Ruyi Zhenbao tablets for patients with lumbar disc herniation: a multicenter, randomized, positive-controlled trial

Acronym

RLDHR

Study objectives

The Ruyi Zhenbao tablets can alleviate clinical symptoms such as pain and lumbar dysfunction in patients with lumbar disc herniation, and their clinical efficacy is not inferior to that of diclofenac sodium sustained-release tablets.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 23/07/2024, Peking University Third Hospital Medical Science Research Ethics Committee (No. 49, Huayuan North Road, Haidian District, Beijing, 100191, China; +86 (0)10 82265573; 1500560252@qq.com), ref: (2024) Ethical Review No. (545-02)

Study design

Multicenter randomized positive control trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lumbar disc herniation

Interventions

Eligible patients who meet the inclusion and exclusion criteria will be randomly assigned to either the treatment group or the control group, with 200 patients in each group. The randomization sequence will be generated using SAS software, a programming language and environment designed for statistical computations. To ensure allocation concealment, the study

drugs will be distributed, packaged, and coded by independent researchers. Hospital research staff will be responsible for managing drug distribution, and upon patient enrollment, they will assign the corresponding drug sequence numbers to the respective participants.

Before treatment, all patients will undergo a general physical examination, magnetic resonance imaging (MRI) or computed tomography (CT) scan, and laboratory tests (including routine blood and urine tests, as well as liver and kidney function tests). The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) Pain Scale will be used to screen patients for neuropathic pain. For those who meet the inclusion criteria and are enrolled in the study, relevant traditional Chinese medicine (TCM) symptom characteristics will be recorded. Additionally, a series of assessments will be conducted, including the Visual Analog Scale (VAS) for pain (assessing both lower back and leg pain separately), the VAS for numbness, the Japanese Orthopaedic Association (JOA) Back Pain Evaluation Questionnaire, the Oswestry Disability Index (ODI), and the recording of concomitant or co-administered medications (including drug names, dosages, and frequencies).

During the treatment phase, patients in the treatment group will receive Ruyi Zhenbao tablets, while those in the control group will receive diclofenac sodium sustained-release tablets. Participants may continue using their regular medications for underlying conditions, such as antihypertensives, antidiabetics, or lipid-lowering agents, throughout the clinical study. The treatment regimen for the treatment group will consist of Ruyi Zhenbao Tablets administered orally at a dose of 2 g twice daily for a period of 4 weeks. The control group will receive Diclofenac Sodium Sustained-Release Tablets, taken orally at a dose of 75 mg once daily for 4 weeks.

If a patient's VAS score reaches or exceeds 7 points on the 0 to 10 scale, rescue therapy will be initiated, which may include nonsteroidal anti-inflammatory drugs (NSAIDs), diuretics, and/or corticosteroids. The use of traditional Chinese medical treatments, such as infrared irradiation, cupping, acupuncture, or Chinese herbal medicine, is prohibited during the study. Following the completion of treatment, patients will be followed up for an additional 4 weeks.

Intervention Type

Supplement

Primary outcome(s)

1. Lower back and leg pain assessed using a Visual Analogue Scale (VAS) at baseline, and at the end of the 1st, 2nd and 4th weeks of treatment, as well as during the 2nd and 4th weeks of follow-up after the treatment concludes.
2. Lumbar function and symptoms evaluated using the Japanese Orthopaedic Association (JOA) score at baseline, after the 2nd and 4th weeks of treatment, and during the 2nd and 4th weeks of follow-up post-treatment.

Key secondary outcome(s)

1. Lower back and leg numbness measured using a VAS at baseline, and at the end of the 2nd and 4th weeks of treatment, as well as during the 2nd and 4th weeks of follow-up after the treatment concludes.
2. The improvement in functional disability of the subjects is assessed using the Chinese version of the Oswestry Disability Index (ODI) questionnaire at baseline, and at the end of the 2nd, 4th weeks of treatment, as well as during the 2nd and 4th weeks of follow-up after the treatment concludes.
3. After patients in both groups received the start of treatment, the receipt of emergency treatment after adverse events and their respective treatments were recorded.

4. Laboratory tests will include a complete blood count, urinalysis, liver function tests (ALT, AST, ALP, TBIL, γ -GT), and kidney function tests (Scr) at baseline, with liver and kidney function tests repeated after 4 weeks of treatment.
5. Adverse events occurring during the intervention and follow-up periods will be documented for both groups.

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Patient who meets the diagnostic criteria for lumbar disc herniation: with the guidance from the diagnostic criteria for lumbar disc herniation as outlined in the following guidelines: an evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy from the North American Spine Society (NASS, 2014), Clinical practice guideline for diagnosis and treatment of lumbar disc herniation(2020) from Chinese Orthopaedic Association of Spinal Surgery Group and Chinese Orthopaedic Association of Orthopaedic Rehabilitation Group, and the Chinese Pain Expert Consensus on the Diagnosis and Treatment of Lumbar Disc Herniation (2020). The diagnostic criteria for this study require that patients meet at least three of the first six criteria listed below, in combination with the seventh criterion (If the patient has had a CT or MRI within the past three months that provides sufficient information for a clinical diagnosis, further imaging is not required. However, if the previous imaging report is insufficient, a repeat examination is necessary). The criteria for diagnosing lumbar disc herniation are as follows:

1.1. Low back pain

1.2. Radiating pain in the lower limbs, corresponding to the distribution of the affected nerve

1.3. Sensory disturbances in the lower limbs, with decreased superficial sensation in the skin areas corresponding to the affected nerve

1.4. Positive Straight Leg Raise (SLR) test, Positive SLR enhancement test, Positive Contralateral SLR test, or Positive Femoral Nerve Stretch test

1.5. Diminished tendon reflexes compared to the healthy side

1.6. Decreased muscle strength

1.7 MRI or CT of the lumbar spine showing a herniated disc with nerve compression and symptoms and signs consistent with those of the involved nerve

2. Patients must present with symptoms of pain, numbness, or muscle tension in the lower back and/or lower limbs.

3. Patients must exhibit limited lumbar mobility, such as inability to bend forward, difficulty turning over in bed, or inability to sit for more than one hour.

4. Patient's Visual Analog Scale (VAS) score for pain: $30 \text{ mm} \leq \text{VAS} < 70 \text{ mm}$

5. Oswestry Disability Index (ODI) Score: $20\% < \text{ODI} \leq 80\%$

6. 18-65 years old

7. Patients must voluntarily agree to participate in the study and sign the informed consent form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Patients with combined spondylolisthesis or severe nucleus pulposus protrusion causing significant cauda equina nerve compression, or substantial and progressive loss of motor function, or those with clear surgical indications who are unsuitable for conservative treatment
2. Patients suffering from other diseases with symptoms of lower back and leg pain, such as lumbar spinal stenosis, spondyloarthritis, ankylosing spondylitis; other possible diseases include but are not limited to osteoporosis, tumors, or herpes zoster virus infection, visceral diseases (such as pelvic inflammatory disease, appendicitis, or cholecystitis), gynecological diseases, muscle or ligament strains
3. Patients allergic to the study drug or with an allergic constitution, or those with contraindications to drug use
4. Patients with severe cardiovascular, cerebrovascular, liver, kidney diseases, or severe primary systemic diseases
5. Patients with mental disorders or dementia who are unable to cooperate in completing the clinical study
6. Pregnant or breastfeeding women
7. Patients who are simultaneously participating in other clinical trial studies
8. Patients involved in litigation or legal claims

Date of first enrolment

23/09/2024

Date of final enrolment

23/09/2025

Locations

Countries of recruitment

China

Study participating centre

Peking University Third Hospital

No. 49, Huayuan North Road, Haidian District

Beijing

China

100191

Study participating centre

Guangdong Provincial Hospital of Chinese Medicine

No. 111, Dade Road, Yuexiu District

Guangzhou

China

510120

Study participating centre

The Third Hospital of Hebei Medical University

No. 139, Ziqiang Road, Qiaoxixiang District

Shijiazhuang

China

050051

Study participating centre

The First Hospital of Lanzhou University

No.1 Donggang West Road, Chengguan District

Lanzhou

China

730000

Study participating centre

The First Affiliated Hospital of Henan University

No. 357, Ximen Street

Kaifeng

China

475004

Study participating centre

Liuzhou People's Hospital

No. 8 Wenchang Road, Chengzhong District

Liuzhou

China

545006

Study participating centre

The Affiliated Hospital of Qingdao University

No. 16 Jiangsu Road, Southern District

Qingdao
China
266000

Study participating centre
The First Affiliated Hospital of Soochow University
No. 899, Pinghai Road, Gusu District
Suzhou
China
215006

Sponsor information

Organisation
Tibet Cheezheng Tibetan Medicine Co., Ltd (china)

Funder(s)

Funder type
Industry

Funder Name
Tibet Cheezheng Tibetan Medicine Co., Ltd (China)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date