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Efficacy and safety of the Tibetan medicine 'Baimai ointment' for patients with pain due to lumbar disc herniation

Submission date
15/10/2021

Recruitment status
No longer recruiting

Registration date
25/10/2021

Overall study status
Completed

Last Edited
06/11/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Lumbar disc herniation, also known as a 'slipped disc', is when a soft cushion of tissue between the bones in your spine pushes out. It's painful if it presses on nerves.
Patients with lumbar disc herniation (LDH) usually suffer from pain and numbness in the lower back and lower limbs and even urination and defecation function disturbance. Non-surgical treatment, as the first-line treatment for most patients with LDH, includes rest, physical therapy, traditional Chinese medicine, and meditation, for relieving symptoms and improve lumbar spinal joint dysfunction.
Baimai ointment is a Tibetan medicine for external use which is composed of natural ingredients: Curcuma longa L., Myristica fragrans Houtt., Nardostachys chinensis DC., Actinolite, Glycyrrhiza uralensis Fisch., Moschus sifanicus Przewalski., Zingiber officinale Rosc., Carum carvi L., Acorus calamus L., Zanthoxylum bungeanum Maxim. and Trona. It has effects on relieving rigidity of muscle and activating collateral, and can effectively improve the skeletal and muscular system diseases and neurological diseases including lumbar disc herniation. Previous clinical studies showed that Baimai ointment could relieve pain and lumbar spinal joint dysfunction in patients with LDH. This study aims to evaluate the effectiveness and safety of Baimai ointment for LDH.

Who can participate?
Patients aged between 18 and 65 with lumbar disc herniation, whose pain score (0-10) is 4 points or more

What does the study involve?
Participants will be randomly divided into two groups (treatment group and control group). Patients in the treatment group will be treated with Baimai ointment and patients in the control group will be treated with placebo (dummy ointment). Rescue treatment as nonsteroidal anti-inflammatory drugs, dehydrating drugs, and (or) hormones will be added when pain is scored greater than or equal to 7. The lumbar spinal joint dysfunction, degree of lower back and legs pain, numbness, the proportion of the two groups receiving Rescue treatment, and compliance with health education will be evaluated for the effectiveness of the ointment. All patients will be treated for 2 weeks and followed up for 1 week after the end of treatment.

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 skin irritation, such as erythema and pigmentation.

Where is the study run from?
Beijing University of Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
August 2020 to February 2022

Who is funding the study?
Gansu Cheezheng Tibetan Medicine Co., Ltd. (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
202106v5.0

Study information

Scientific Title
Efficacy and safety of Baimai ointment for patients with lumbar disc herniation: a multicenter, randomized, double-blind, placebo-controlled trial

Acronym
BLDHR

Study objectives
Baimai ointment can improve lumbar spinal joint dysfunction and clinical symptoms for patients with lumbar disc herniation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/06/2021, Ethics Committee of Wang Jing Hospital of CACMS (Huajiadi Street, Chaoyang District, Beijing; +86 (0)10 84739047; email not available), ref: WJEC-KT-2021-033-P003

Study design
Multi-center randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Lumbar disc herniation

Interventions
Patients who meet the inclusion and exclusion criteria will be randomly divided into the treatment group and control group, with 97 patients in each group. The random sequence is generated using R, a programming language and software environment for statistical computing. As allocation concealment, the drugs used in the study will be distributed, packaged and coded by independent researchers. The scientific research personnel in hospitals will take

care of the drugs and distribute the corresponding serial number of drugs to the corresponding participants after the enrollment.

Before treatment, general physical examination, magnetic resonance imaging (MRI) or computed tomography (CT) examination, and laboratory tests (blood and urine routine, liver and kidney function) will be conducted while the degree of dysfunction, pain and numbness will be scored.

During the treatment period, patients in the treatment group will be applied with Baimai ointment, and patients in the control group will be applied with placebo ointment. Participants can continue to take medicines for their underlying diseases, such as antihypertensive drugs, hypoglycemic drugs, lipid-lowering drugs, during the clinical research period. Baimai ointment and placebo will be used twice a day for 2 consecutive weeks. For participants with lower back pain and numbness, the ointment is smeared on both sides of the back from the 3rd, 4th and 5th lumbar vertebra to the 1st sacral vertebra. For those accompanied with leg pain, numbness, etc., the Huantiao acupoint (GB30) on the affected side can be applied on the basis of the above parts. The dosage is 5-8g on the lower back each time and 1g on each side of the Huantiao acupoint, rubbing 3-5 minutes until the medicine is absorbed.

Rescue therapy as nonsteroidal anti-inflammatory drugs, dehydrating drugs and (or) hormones will be added when the visual analogue scale (VAS) is scored ≥7 (scale of 0 to 10). Traditional Chinese medicine therapies will not be allowed to use as a combination, such as infrared radiation and cupping, acupuncture, Chinese patent medicine, etc. Patients will be followed up for 1 week after the end of treatment.

Intervention Type
Supplement

Primary outcome measure
1. Lumbar spinal joint dysfunction measured using a Japanese orthopaedic association scores (JOA, 0-29 points) at baseline, after 1st week of treatment, after 2nd week of treatment, and at 1 week of follow-up after the end of treatment.
2. Lower back and leg pain measured using a visual analogue scale (VAS, 0-10 points) at baseline, every day during treatment, and after 1 week of follow-up after the end of treatment.

Secondary outcome measures
1. Lower back and leg numbness measured using a 4-point Likert scale (0-3 points) at baseline, every day during treatment, and after 1 week of follow-up after the end of treatment.
2. The proportion of the two groups receiving rescue therapy and their respective treatment methods, such as the name, frequency, usage and dosage of the medicines used.
3. Compliance with health education every day during treatment and during follow-up for 1 week after the end of treatment. The items of health education include wearing waist circumference, bed rest and other measures (protection from cold and warmth, avoiding excessive fatigue, avoiding excessive torsion or flexion, and excessive weight bearing of the lower back).

Overall study start date
01/08/2020

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Participants who meet the diagnostic criteria based on the Chinese Pain Expert Consensus on the Diagnosis and Treatment of Lumbar Disc Herniation published by the Spine-derived Pain Section, Pain Branch, Chinese Medical Association, in 2020
2. Participants with pain and/or numbness and muscle tension in the lower back and lower limbs
3. Participants with visual analogue scale (VAS, 0-10 points) scored ≥4 points
4. Participants aged between 18 to 65 years old
5. Participants who are volunteer to participate in the study and sign the informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
194 participants (97 in each group)

Total final enrolment
194

Key exclusion criteria
1. Participants with spondylolisthesis or herniated nucleus pulposus severely compressing the cauda equina, or with obvious surgical indications and not suitable for conservative treatment
2. Participants suffering from other diseases with lower back pain symptoms, such as ankylosing spondylitis, etc.
3. Participants who are allergic to the study drugs (Baimai ointment)
3. Participants suffering from severe cardiovascular, cerebrovascular, liver, and kidney diseases
4. Participants suffering from mental diseases or senile dementia who cannot cooperate with the clinical research
5. Women during pregnancy or lactation
6. Participants with skin ulceration at the affected joint(s)
7. Participants with skin ulceration on the lower back
8. Participants who participate in other clinical trials at the same time

Date of first enrolment
25/08/2021

Date of final enrolment

Locations

Countries of recruitment
China

Study participating centre
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
1. The study protocol will be submitted to a peer-reviewed journal.
2. The results will be submitted to a peer-reviewed journal.

Intention to publish date
31/12/2022

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/10/2023	06/11/2023	Yes	No