**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: March 10, 2025

**ClinicalTrials.gov ID: NCT06872918**

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | ZSLL-KY-2024-080-01 |
| Brief Title: | A Biomechanical Study of the Lumbar Intervertebral Disc by Lever Positioning Manipulation |
| Official Title: | Study on the Stress-Strain and Flow-Solid Coupling Effects on Lumbar Intervertebral Discs Under Transient Loading by Lever Positioning Manipulation With Different Triggering Modes |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | February 2025 |
| Overall Status: | Recruiting |
| Study Start: | January 1, 2024 [Actual] |
| Primary Completion: | June 30, 2028 [Anticipated] |
| Study Completion: | December 31, 2028 [Anticipated] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | The Third Affiliated hospital of Zhejiang Chinese Medical University |
| Responsible Party: | Principal Investigator<br>Investigator: Longhao Chen [LChen]<br>Official Title: Principal Investigator<br>Affiliation: The Third Affiliated hospital of Zhejiang Chinese Medical University |
| Collaborators: | |

## 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<br>Approval Number: ZSLL-KY-2024-080-01<br>Board Name: Medical Ethics Committee of The Third Affiliated Hospital of Zhejiang University of Traditional Chinese Medicine<br>Board Affiliation: The Third Affiliated Hospital of Zhejiang University of Traditional Chinese Medicine |

Phone:
Email: 842904345@qq.com
Address:

Zhejiang University of Traditional Chinese Medicine, No. 548, Binwen Road, Binwen District, Hangzhou, Zhejiang Province, China

Data Monitoring:

## Study Description

Brief Summary: Purpose of Study:

The purpose of this clinical trial is the clinical efficacy of different trigger modes of lever positioning manipulation (LPM) for the treatment of lumbar disc herniation (LDH). At the same time, the investigators considered from the perspective of virtual simulation and applied 3D finite element technology combined with dynamic capture system and mechanical sensing system to comprehensively evaluate the characteristics of biomechanical effects of different triggering modes of LPM on LDH.

The main questions ansthe investigatorsred are:

(1) To clarify what is the clinical effect of LPM in treating lumbar disc herniation? (2) Summarize the spatial motion laws and mechanical characteristics of the two triggering modes of LPM. Analyze the correlation betthe investigatorsen the LPM operation characteristics and the individual characteristics of LDH patients as the investigatorsll as the imaging parameters, and clarify the differences betthe investigatorsen the two LPM two trigger modes.(3) To analyze the stress-strain effects of the two LPM triggering modes on the L4/5 intervertebral discs and related accessory structures in different zones, and to elaborate the optimal type of LPM triggering modes for the treatment of LDH from the biomechanical point of view.(4) Under the condition of porous elasticity of the intervertebral discs, the investigators will study the effects of transient load on the flow-solid coupling of the intervertebral discs with different degrees of degeneration at L4/5 in the two triggering modes of the LPM, so as to reveal the mechanism of the LPM intervention in the intervertebral discs' degeneration.

The main research includes the following four aspects:

(1) Clinical efficacy study and standardized data collection of LPM.This study plans to recruit 128 volunteers from the Third Hospital Affiliated to Zhejiang University of Traditional Chinese Medicine will be recruited for the study. Sixty-four LDH patients and 64 healthy volunteers the investigatorsre planned to be included in this study. The LDH patients the investigatorsre divided into lever positioning manipulation group (group 1, n=32) sham manipulation group (group 2, n=32) using random number table method. In this group, unilateral wrenching mode was used for patients with paracentral LDH and bilateral wrenching mode was used for patients with central LDH. Manipulation was performed every two days, receiving a total of 6 sessions over 2 the investigatorseks. Healthy volunteers the investigatorsre similarly categorized into unilateral trigger mode group (group 3, n=32) bilateral trigger mode group (group 4, n=32) using random number table method. LPM treatments the investigatorsre administered every two days, receiving a total of 6 sessions over 2 the investigatorseks. Participants in both Group 1 and Group 2 the investigatorsre required to complete clinical questionnaire assessments, including the Visual Analog Scale (VAS) and the Japanese Orthopaedic Association (JOA) scoring system. During the LPM operation, the performer wore a mechanical sensing glove to collect the mechanical parameters of the maneuver, while a motion capture system was used to collect the kinematic parameters of the LPM, and the individual characteristics and imaging parameters of all the volunteers the investigatorsre

collected, so as to analyze the correlation betthe investigatorsen the mechanical parameters, kinematic parameters, and the individual factors of the patients with LDH.(2) Virtual simulation model building and maneuver loading analysis.One standard volunteer was selected among 64 healthy volunteers, and the lumbar spine-pelvis imaging CT data the investigatorsre imported into Mimics software for geometric model extraction and preliminary processing. Geomagic and other software the investigatorsre utilized to construct the lumbar spine 3D finite element simulation model. And based on Abaqus CAE finite element simulation software, two kinds of wrenching mode maneuvers of LPM the investigatorsre simulated and loaded. The kinematic and mechanical parameters of the LPM the investigatorsre disassembled and loaded into each model to obtain the analytical models of manipulation in different trigger modes. The experimental results the investigatorsre obtained by calculating and analyzing the working conditions of LPM through Abaqus software. Observe the stress and strain on the intervertebral disc and ancillary structures under the action of LPM in different pulling modes.(3) Fluid-solid coupling effect of LPM on lumbar intervertebral disc under transient loads.Under the condition of considering the porous elasticity of the intervertebral disc, the coupled flow-stress simulation in Abaqus CAE was utilized to study the coupled flow-solid effect of the intervertebral disc, and then loaded to simulate the LPM manipulation, and observed the changes such as the stress displacement of the intervertebral disc under the manipulation.

Detailed Description:

## Conditions

Conditions: Lumbar Disc Herniation

Keywords:

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 128 [Anticipated]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Lever positioning manipulation patient group | Procedure/Surgery: Lever positioning manipulation<br>The patient was placed in the prone position, and the doctor used one-finger Zen pushing, rolling, pressing and kneading, flicking and plucking methods in the patient's lumbar region and the affected side of the lower limb pain repeated massage treatment for 15min; the patient was placed in the prone open-mouth position, and the operator stood on the right side of his/her body, so that the whole body of the |

| Arms | Assigned Interventions |
|---|---|
| | patient's muscles were relaxed. According to the type of herniation, the patient with paracentral lumbar disc herniation performed unilateral triggering mode, and the patient with central lumbar disc herniation performed bilateral triggering mode. |
| Sham Comparator: Sham manipulation patient group | Procedure/Surgery: Cluster of pseudo-manipulators<br>Sham manipulation treatment was given. Recipients take the prone position, the medical practitioner with a finger Zen push method, rolling method, pressing and kneading method, flicking and plucking method in the patient's lumbar region and the affected side of the lower limbs of the pain in the repeated massage treatment for 15min; patients prone position, with traction rope fixed lumbar disc herniation side of the affected limb, so that the affected limb back to the maximum extent of the extension, and then release the traction rope, simulating the backward extension of the force of the lever positioning manipulation, the medical practitioner does not do any manipulation. |
| Experimental: Lever Positioning Manipulation Unilateral Trigger Mode Healthy Volunteer Groups | Procedure/Surgery: Mechanics and kinematics data acquisition of unilateral wrenching patterns in lever positioning manipulation<br>During the unilateral trigger mode operation of the lever positioning manipulation, the operator wears a mechanics sensing glove to collect the mechanics parameters of the manipulation, including: hand preload force, hand trigger maximum force, elbow compression preload force, and elbow compression maximum force. At the same time, a motion capture system was used to collect the kinematic parameters of the lever positioning manipulation, including: loading backward extension angle, loading backward extension trigger angle, average trigger time, maximum speed, and maximum acceleration. |
| Experimental: Lever Positioning Manipulation Bilateral Trigger Patterns Healthy Volunteer Groups | Procedure/Surgery: Mechanics and kinematics data acquisition of bilateral wrenching patterns in lever positioning manipulation<br>During the bilateral triggering mode operation of the lever positioning manipulation, the operator wore a mechanics sensing glove to collect the mechanics parameters of the manipulation, including: hand preload force, hand triggering maximum force, elbow pressing preload force, and elbow pressing maximum force. At the same time, a motion capture system was used to collect the kinematic parameters of the lever positioning manipulation, including: loading backward extension angle, loading backward extension trigger angle, average trigger time, maximum speed, and maximum acceleration. |

## Outcome Measures

Primary Outcome Measure:

1. Overall effective rate of clinical efficacy
   The efficacy was evaluated according to the Criteria for Diagnosis and Efficacy of Traditional Chinese Medicine (TCM) Diseases and Evidence issued by the State Administration of Traditional Chinese Medicine (SATCM) of China in

1994. Total effective rate = (cured + apparent effect + effective) / total number of cases × 100 percent. The efficacy is categorized into the following four grades:cured#apparent effect #effective#ineffective.

Units of Measure: percentage. Aggregation Method: Calculate the total effective rate.

[Time Frame: 2 weeks]

Secondary Outcome Measure:

2. Pain Visual Analogue Scale (VAS)
   Pain level was assessed using the VAS scale. The patient marks the level of pain on a 10 cm long line, with 0 indicating no pain and 10 indicating the worst pain. Higher scores indicate more severe pain.

   Units of Measure: score (0-10). Aggregation Method: reports the mean or median score.

   [Time Frame: 2 weeks]
3. JOA Score for Low Back Pain (Japanese Orthopaedic Association Score for Low Back Pain)
   Patients were evaluated for signs, symptoms, and dysfunction using the JOA scoring system for low back pain. Scores range from 0 to 29, with higher scores indicating less severe low back pain symptoms and better functional recovery.

   Units of Measure: score (0-29). Aggregation Method: reports the mean or median score.

   [Time Frame: 2 weeks]
4. Mechanical parameters during manipulation of the maneuver
   The operator wears a manipulative mechanics measurement glove and elbow sleeve and secures it, and performs the manipulation at the recipient's waist. Mechanical parameters were collected by means of pressure transducers, including: hand preload force, hand trigger maximum force, elbow compression preload force, and elbow compression maximum force.

   Units of Measure: Force (Newton, N) Aggregation Method: reports the average or peak value for each parameter.

   [Time Frame: 1 week for 3 times]
5. Kinematic parameters at the time of manipulation
   The Marker points of the motion capture system were placed by the applicator and the patient, and after the motion capture system was calibrated successfully, the manipulation was performed at the waist of the patient. Measurement of kinematic parameters, including: loaded back extension angle, loaded back extension trigger angle.

   Units of Measure:

   - Angle (degrees, °) Aggregation Method: reports the average or peak value for each parameter.

   [Time Frame: 1 week for 3 times]
6. Average trigger time at the time of manipulation
   The Marker points of the motion capture system were placed by the applicator and the patient, and after the motion capture system was calibrated successfully, the manipulation was performed at the waist of the patient. Measurement of kinematic parameters, including: average trigger time.

   Units of Measure:

   -Time (sec, s) Aggregation Method: reports the average or peak value for each parameter.

   [Time Frame: 1 week for 3 times]
7. Maximum speed at the time of manipulation
   The Marker points of the motion capture system were placed by the applicator and the patient, and after the motion capture system was calibrated successfully, the manipulation was performed at the waist of the patient. Measurement of kinematic parameters, including: maximum speed.

   Units of Measure:

   -Velocity (deg/sec, °/s) Aggregation Method: reports the average or peak value for each parameter.

   [Time Frame: 1 week for 3 times]
8. Maximum acceleration at the time of manipulation

The Marker points of the motion capture system were placed by the applicator and the patient, and after the motion capture system was calibrated successfully, the manipulation was performed at the waist of the patient. Measurement of kinematic parameters, including: maximum acceleration.

Units of Measure:

-Acceleration (deg/sec², °/s²) Aggregation Method: reports the average or peak value for each parameter.

[Time Frame: 1 week for 3 times]

## Eligibility

| | |
|---|---|
| Minimum Age: | 20 Years |
| Maximum Age: | 60 Years |
| Sex: | All |
| Gender Based: | |
| Accepts Healthy Volunteers: | Yes |

Criteria: Inclusion Criteria:

Healthy volunteers:

1. Healthy subjects with no history of lumbar spine disease, aged 20 to 60.
2. No obvious lumbar spine pain or previous diagnosis of lumbar spine-related disease.
3. Willing to participate in the study and have signed an informed consent form.

Patients:

1. Aged 20 to 60 years.
2. Diagnosed with L4-L5 lumbar disc herniation by CT or MRI.
3. Stable vital signs, no serious systemic diseases, and no complications.
4. Willing to accept manipulation as a test subject.

Exclusion Criteria:

1. Lumbar vertebrae fracture or dislocation.
2. Lumbar spine or lumbar soft tissue tumor, tuberculosis.
3. Lumbar spine fusion, paravertebral bone bridges, or severe osteoporosis.
4. History of lumbar spine surgery.
5. History of serious lumbar trauma.
6. Lumbar skin inflammation, skin breaks, or other skin conditions.
7. Serious primary diseases of the cardiac, hepatic, renal, or hematopoietic systems; psychiatric patients.
8. Extreme frailty or pregnancy.
9. Participation in other manipulative therapies that may interfere with the study.
10. Intolerable adverse reactions.

## Contacts/Locations

Central Contact Person: Longhao Chen, Principal Investigator
Telephone: 18878980512
Email: 842904345@qq.com

Central Contact Backup:

Study Officials:

Locations: **China, Zhejiang**
The Third Affiliated Hospital of Zhejiang University of Traditional Chinese Medicine
[Recruiting]
Hangzhou, Zhejiang, China, 310005

## IPDSharing

Plan to Share IPD:

## References

Citations:

Links:

Available IPD/Information: