

Studying the effect and safety of percutaneous endoscopy operation combined with platelet-rich plasma injection for treating lumbar disc herniation in young and middle-aged

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		<input type="checkbox"/> Protocol
Registration date 05/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/09/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Lumbar disc herniation (LDH) is a spinal condition where part of a disc in the lower back pushes out and presses on nearby nerves. Percutaneous endoscopic lumbar discectomy (surgery to remove part of the herniated disc) has become widely used for LDH due to its significant advantages and is now the preferred surgical method for simple LDH. While effective in nerve decompression, it lacks methods for repairing the degenerated discs. Platelet-rich plasma (PRP), rich in various growth factors, has shown good potential for disc repair. Currently, there are few clinical studies combining percutaneous endoscopic surgery with PRP for treating LDH. The aim of this study is to assess the clinical effectiveness and safety of percutaneous endoscopic nucleotomy combined with PRP injection for treating LDH in young and middle-aged adults.

Who can participate?

Patients aged 18-55 years with LDH that is unresponsive to 1 month of conservative treatment

What does the study involve?

The patients were randomly divided into observation and control groups. The observation group underwent percutaneous endoscopic nucleotomy combined with PRP gel injection into the disc, while the control group underwent percutaneous endoscopic nucleotomy only.

What are the possible benefits and risks of participating?

Spinal endoscopic nucleotomy with PRP injection provides minimally invasive nerve decompression and promotes tissue repair, leveraging the advantages of both treatment methods. The possible risks are infection and increased surgical costs.

Where is the study run from?

Zhongshan Torch Development Zone People's Hospital (China)

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

January 2022 to December 2024

Who is funding the study?

Zhongshan City Science and Technology Bureau (China)

Who is the main contact?

Hairu Qi, qhr10363@163.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Mr Hairu Qi

Contact details

Dept of Orthopaedic

Zhongshan Torch Development Zone People's Hospital

Zhongshan

China

528437

+86 (0)13549845311

qhr10363@163.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Percutaneous endoscopic nucleotomy combined with platelet-rich plasma injection for treating lumbar disc herniation in young and middle-aged

Study objectives

The effect of percutaneous spinal endoscopy in the treatment of lumbar disc herniation (LDH) is positive. It is effective for nerve decompression, but there is no good repair method for degenerative intervertebral discs. Platelet-rich plasma (PRP) has a good effect on intervertebral disc repair because it is rich in various growth factors. At present, there are few clinical studies

on the treatment of LDH by percutaneous endoscopic spine surgery combined with PRP. This study aims to observe the clinical efficacy and safety of spinal endoscopic surgery combined with PRP in the treatment of LDH. Better results are expected.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/01/2022, Medical ethics committee of Zhongshan Torch Development Zone People's Hospital (No. 123 Yixian Road, Torch Development Zone, Zhongshan, 528437, China; +86 (0)760 28106091; 1649328315@qq.com), ref: (2022)-0001

Study design

Single-center single-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Lumbar disc herniation

Interventions

From April 2022 to December 2023, 60 patients with LDH were randomly divided using the random number table method into two groups of 30 each. The observation group underwent percutaneous endoscopic nucleotomy combined with autologous PRP gel injection into the disc, while the control group underwent percutaneous endoscopic nucleotomy alone. Visual Analogue Scale (VAS) scores and Oswestry Disability Index (ODI) scores were recorded and compared preoperatively, 3 days postoperatively, 3 months postoperatively, and 6 months postoperatively. The modified Macnab criteria were used for efficacy evaluation at the final follow-up. MRI Pfirrmann grading of the operated disc segment and complications were also assessed preoperatively and at the final follow-up.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Pain intensity measured using the Visual Analogue Scale (VAS) preoperatively, 3 days postoperatively, 3 months postoperatively, and 6 months postoperatively

2. Degree of disability measured using the Oswestry Disability Index (ODI) preoperatively, 3 days postoperatively, 3 months postoperatively, and 6 months postoperatively
3. Clinical efficacy evaluated using the modified MacNab criteria for the excellent and good rate at the final follow-up

Secondary outcome measures

1. Pfirrmann grading of the operated disc segment using MRI preoperatively and 6-9 months postoperatively
2. Incidence of complications recorded during follow-up

Overall study start date

01/01/2022

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. Age 18-55 years
2. Diagnosed with LDH, with significant radicular symptoms and positive straight leg raise test, unresponsive to 1 month of conservative treatment
3. Single-segment responsible for surgery

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Both

Target number of participants

80

Total final enrolment

60

Key exclusion criteria

1. Lumbar infection, tumors, or severe deformities, lumbar instability or spondylolisthesis
2. Blood system-related diseases

3. History of long-term treatment with NSAIDs or immunosuppressants before surgery
4. Significant calcification or bony stenosis of the responsible lumbar disc
5. Psychiatric disorders that prevent full cooperation with treatment

Date of first enrolment

01/04/2022

Date of final enrolment

30/09/2023

Locations

Countries of recruitment

China

Study participating centre

Zhongshan Torch Development Zone People's Hospital

No. 123 Yixian Road

Torch Development Zone

Zhongshan

China

528437

Sponsor information

Organisation

Zhongshan Science and Technology Bureau

Sponsor details

No.1 Songyuan Road

Zhongshan

China

528400

+86 (0)760 88315063

zsskjjfzk@163.com

Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

Zhongshan Science and Technology Bureau

Alternative Name(s)

Zhongshan Municipal Bureau of Science and Technology,

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

China

Results and Publications

Publication and dissemination plan

Plan to publish in a highly influential peer-reviewed journal

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

Datasets generated and/or analyzed during the current study will be available upon request from Hairu Qi, qhr10363@163.com

IPD sharing plan summary

Available on request