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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

Submission date
14/08/2024

Recruitment status
No longer recruiting

Registration date
05/09/2024

Overall study status
Completed

Last Edited
04/09/2024

Condition category
Musculoskeletal Diseases

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

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
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528437

Sponsor information

Organisation
Zhongshan Science and Technology Bureau

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

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