ISRCTN17213765 https://doi.org/10.1186/ISRCTN17213765

A study comparing two minimally invasive injection-based treatments for lumbar disc herniation

Submission date
18/05/2026

Recruitment status
No longer recruiting

Registration date
18/06/2026

Overall study status
Completed

Last Edited
26/05/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Lumbar disc herniation (often called a slipped disc) is a common cause of low back pain and leg pain. Standard treatments, such as physiotherapy, pain medication, steroid injections, and surgery, may help some patients, but they do not always provide long-lasting improvement. This study aims to compare two minimally invasive treatment approaches for lumbar disc herniation.

Who can participate?
Patients aged 18 years or older with symptoms of lumbar disc herniation, such as low back pain with or without pain spreading to one leg

What does the study involve?
Participants are randomly assigned to one of two treatment groups. One group receives non-standardized ultrasound-guided injections of platelet-rich plasma and hyaluronic acid. The other group receives a standardized nanosurgery (a precise medical procedure) and bioengineered regenerative therapy protocol (using biological materials to help the body heal). This consists of one initial tissue release procedure followed by four stages of combined tissue release and regenerative treatment over 8 to 12 weeks. Before treatment, all participants undergo clinical assessment and imaging, including MRI and ultrasound examination of the lower spine. Pain and disability are assessed before treatment and again after 12 months using standard questionnaires. MRI is also performed before treatment and at 12 months.

What are the possible benefits and risks of participating?
Participants may experience improvement in pain, function, and daily activity, although this cannot be guaranteed. Possible risks include temporary pain or discomfort at the treatment site, bruising, bleeding, infection, local irritation, or lack of improvement. As with any injection-based or minimally invasive procedure, there may also be rare procedure-related complications.

Where is the study run from?
Wasilczyk Medical Clinic (Poland)

When is the study starting and how long is it expected to run for?
January 2022 to December 2024

Who is funding the study?
Wasilczyk Medical Clinic (Poland)

Who is the main contact?
Dr Cezary Wasilczyk, wasilczyk.chirurg@gmail.com

Contact information

Type(s)
Public, Principal investigator, Scientific

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Study information

Scientific Title
A randomized controlled trial evaluating the efficacy and safety of standardized nanosurgery and bioengineered regenerative therapy compared with orthobiologic injections in patients with lumbar disc herniation

Study objectives
Primary objective:
To compare the effect of standardised nanosurgery and bioengineered therapy versus non-standardized ultrasound-guided orthobiologic treatment on functional disability, measured using the Oswestry Disability Index, in patients with lumbar disc herniation.

Secondary objectives:
1. To compare pain intensity between groups using the Visual Analogue Scale (VAS)
2. To assess clinical outcomes at 12-month follow-up
3. To evaluate lumbar spine structural changes on magnetic resonance imaging before treatment and at 12 months

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 18/11/2021, Bioethics Committee of the District Medical Chamber in Warsaw (ul Puławska 18, Warsaw, 02-512, Poland; +48 (0)225428312; j.puchala@oilwaw.org.pl), ref: 52/21

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research

Study type(s)

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

Interventions
The intervention group received a standardized nanosurgery and bioengineered therapy protocol consisting of one initial nanosurgical release followed by four stages of combined nanosurgical and regenerative treatment over 8–12 weeks. Treatment involved ultrasound-guided nano-incisions, nano-fenestration and nano-dissection of fibrotic tissues, followed by regenerative injections using modified platelet-rich plasma with somatotropin and Strophanthus kombe, hyaluronic acid and collagen.

The control group received non-standardized ultrasound-guided orthobiologic injections with platelet-rich plasma and hyaluronic acid, without a predefined structured treatment protocol.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Functional disability measured using the Oswestry Disability Index at baseline and 12 months

Key secondary outcome(s)
1. Pain measured using the VAS scale at baseline and 12 months

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Clinical symptoms consistent with lumbar disc herniation
3. Low back pain with or without unilateral radicular pain
4. MRI-confirmed lumbar disc herniation corresponding to clinical symptoms
5. Ability to understand study procedures and comply with follow-up
6. Written informed consent provided by the participant

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
34

Key exclusion criteria
1. Previous lumbar spine surgery at the index level
2. Urgent indication for surgical intervention, including cauda equina syndrome or progressive neurological deficit
3. Spinal infection, tumour, fracture, or inflammatory spinal disease
4. Significant spinal instability
5. Spondylolisthesis
6. Severe spinal stenosis considered the primary source of symptoms
7. Active infection
8. Coagulation disorders
9. Any contraindication to the planned procedures
10. Pregnancy
11. Inability to provide informed consent
12. Inability to comply with follow-up assessments

Date of first enrolment
01/01/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment

Poland

Sponsor information

Organisation
Wasilczyk Medical Clinic

Funder(s)

Funder type

Funder Name
Wasilczyk Medical Clinic

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data underlying the results reported in this study may be made available by the corresponding author upon reasonable request. Shared data may include baseline characteristics, treatment allocation, VAS and ODI scores at baseline and 12-month follow-up, and anonymized MRI imaging data used for outcome assessment. Data will be shared only after the removal of personal identifiers and subject to approval of a scientifically justified request, in accordance with ethical approval, participant consent, and applicable data protection regulations.

IPD sharing plan summary
Available on request