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Using ultrasound to guide pain relief during minimally invasive spine surgery

Submission date	Recruitment status	[_] Prospectively registered
31/03/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/04/2025	Surgery	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study explores whether ultrasound-guided erector spinae plane block (ESPB) can improve the surgical experience of patients undergoing PTED for lumbar disc herniation, compared to traditional local anesthesia.

Who can participate?
Adults aged 18–65 years with confirmed single-level lumbar disc herniation who have failed conservative treatment.
Participants will be excluded if they:
(1)patients with surgical contraindication; (2) multiple segments of disc herniation, vertebral infection or tumor; (3) lumbar spondylolisthesis, obvious degenerative deformities, instability, and scoliosis; (4) substantial diseases of important organs; and (5) patients who withdrew their participation.

What does the study involve?
Clinical Application of Ultrasound-guided Erector Spinae Plane Block in Percutaneous Transforaminal Endoscopic Discectomy
What are the possible benefits and risks of participating?
ESPB may provide better intraoperative comfort and stability. Risks are minimal, as both techniques are standard and widely used.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study is being conducted at the Dehua County Hospital, Fujian Province (China)

When is the study starting and how long is it expected to run for?
May 2021 to December 2021

Who is funding the study?
Dehua County Hospital (China)

Who is the main contact?
Xiaoting Zheng, No. 32 Xunzhong Town, Dehua County, Quanzhou City, Fujian Province, China
E-mail:1540635330@qq.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Ms Xiaoting Zheng

ORCID ID
http://orcid.org/0000-0003-3458-1424

Contact details
No. 32 Xunzhong Town, Dehua County, Quanzhou City
Quanzhou
China
362500
+86 15377986263
1540635330@qq.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomized controlled trial comparing ultrasound-guided erector spinae plane block versus local anesthesia for pain control and perioperative outcomes in percutaneous transforaminal endoscopic discectomy

Study objectives
Ultrasound-guided erector spinae plane block (ESPB) improves intraoperative comfort, hemodynamic stability, and pain control compared to local anesthesia in PTED, without compromising surgical efficacy or increasing postoperative complications.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 20/05/2021, Dehua County Hospital Medical Ethics Committee (No. 32 Xunzhong Town, Dehua County, Quanzhou City, Fujian Province 362500, Quanzhou, 362500, China; +86 595-23522460; jiang@gmail.com), ref: 2021L[001]

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Ultrasound-guided erector spinae plane block in percutaneous transforaminal endoscopic discectomy

Interventions
Intervention Group (ESPB): The ultrasound-guided erector spinae plane block (ESPB) is administered once prior to surgery. No repeated dosing is involved.

Control Group (LA): Local anesthesia is similarly administered once before surgery.

All participants are followed for a total of 6 months post-operation, with assessments conducted at baseline (pre-operation), 3 months, and 6 months post-operation. These include measurements of pain (VAS), functional status (ODI), and clinical outcomes (modified Macnab criteria).

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Intraoperative VAS scores (Visual Analog Scale) at foraminoplasty, annulus fibrosus operation, and end of surgery.
2. Measured using VAS during the procedure.

Secondary outcome measures
1. Mean arterial pressure (MAP) and heart rate (HR) at four perioperative time points (T0–T3)
2. Operation time, intraoperative blood loss, length of hospital stay

3. Modified Macnab criteria at 3-month follow-up
4. Pre- and postoperative VAS and ODI scores at 3 and 6 months
5. Reoperation willingness on post-op Day 1

Overall study start date
01/05/2021

Completion date
01/12/2021

Eligibility

Key inclusion criteria
1. Invalid conservative treatment for twelve weeks
2. Patients complaining of lower back and lower limb pain or numbness and motor weakness due to LDH
3. Symptoms associated with pre-operative MRI and CT scans
4. None of the patients had a prior history of percutaneous foraminal surgery
5. Imagological examination showing single-segmental LDH without accompanying thickening and calcification of posterior longitudinal ligament and ligamentum flavum

Participant type(s)
Patient

Age group
Adult

Lower age limit
32 Years

Upper age limit
56 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Patients with surgical contraindication
2. Multiple segments of disc herniation, vertebral infection or tumor
3. Lumbar spondylolisthesis, obvious degenerative deformities, instability, and scoliosis
4. Substantial diseases of important organs
5. Patients who withdrew their participation

Date of first enrolment

20/05/2021

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
China

Study participating centre
Dehua County Hospital, Fujian Province
No. 32 Xunzhong Town, Dehua County, Quanzhou City
Quanzhou
China
362500

Sponsor information

Organisation
Dehua County Hospital

Sponsor details
No. 32 Xunzhong Town, Dehua County, Quanzhou City
Quanzhou
China
362500
+86 595-23522460
jiang@gmail.com

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dehua County Hospita

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request E-mail:1540635330@qq.com

IPD sharing plan summary
Available on request