ISRCTN85840831 https://doi.org/10.1186/ISRCTN85840831

UBE spine surgery exploration

Submission date	Recruitment status	[ ] Prospectively registered
19/01/2023	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/01/2023	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/01/2023	Surgery	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A herniated disk in the lower back, also known as a lumbar disk herniation (LDH), is a common indication for spinal surgery. Traditional open discectomy procedures have been replaced by minimally invasive surgery for the benefit of less blood loss and faster recovery. The unilateral biportal endoscopic (UBE) decompression technique is a percutaneous, full endoscopic method that is performed through two small surgical wounds on either side of the spine. UBE offers a large field of vision and working area but has limitations such as being a single-hand manipulation procedure and requiring an assistant for the retraction or holding the endoscope. In this study, new surgical instruments and modifications to the common UBE procedure are being evaluated for safety and efficacy in order to improve clinical outcomes.

Who can participate?
Adult patients with LDH

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given the UBE procedure, which is minimal invasive decompression of the neural element. Participants in the second group are given a classic decompression surgery. At the start of the study and again in follow-up appointments, participants in both groups complete questionnaires in order to find out whether there has been any difference in their pain levels and their ability to perform activities.

What are the possible benefits and risks of participating?
Participants may benefit from reduced pain and early recovery of function due to the UBE procedure. The risks of participating are minor, however, participants may experience pain, swelling or bleeding, wound infection and possible recurrence of the disk herniation after surgery.

Where is the study run from?
Beijing Jishuitan Hospital (China)

When is the study starting and how long is it expected to run for?
January 2020 to January 2031

Who is funding the study?
Beijing Jishuitan Hospital (China)

Who is the main contact?
Dr Xiaozhou Jiang, tony_jxz@126.com (China)

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
YGQ-202208

Study information

Scientific Title
Comparing the outcomes between groups of patients with spine disease treated with unilateral biportal endoscopic decompression technique and other surgeries

Acronym
UBE-JXZ

Study objectives
Unilateral biportal endoscopic (UBE) decompression technique is not inferior than other classic spine surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2021, Beijing Jishuitan Hospital Ethics Committee (Xinjiekou East Street 31, Beijing, China; +86-010-58516688; ethics_jst@163.com), ref: 202101-02

Study design
Prospective randomized controlled trial and retrospective cohort study

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Treatment of spine disease with unilateral biportal endoscopic (UBE) decompression technique and other classic surgeries

Interventions
The study will enroll patients with spine disease, randomize, and assign them to the unilateral biportal endoscopic (UBE) decompression technique treatment group, modification UBE procedure group, and other classic surgery groups. There will then be a period of follow-up and analysis of the clinical outcomes.

UBE lumbar decompression and discectomy.
Materials: We used convention 30° 4-mm rigid arthroscope (BD-1, ShenDa Endoscope, Shenyang, China), 4.0-mm oval burr (Sterling, Conmed-Linvatec, NY, USA), 3.75-mm radiofrequency ablation probe (Super TURBOVAC 90, Smith & Nephew, London, UK) and instruments tool set for UBE decompression (Blon UBE tool set, Blon, Changzhou, China), including neural dissectors, soft tissue dilator, retractor, rotating Kerrison punches and pituitary forceps. Convention K-wire for 0.8 mm in diameter and 175 mm in length and a K-wire bending clamp was also required.

Procedures in steps:
1. Endoscopic portals placement: Under image intensification, a spinal needle is inserted in the paraspinal muscles 1 cm parallel to the midline to localize the desired surgical level. After level confirmation, the needle is removed and two portals 5 mm in diameter are formed using a number 15 surgical blade with a 5 mm handle so that it could be advanced to pierce the fascia which is markedly deep in obese patients. The portals are 1 cm lateral to the midline, with the first directly overlying the intervertebral disc and are used for the introduction of the arthroscope and the second is 3–4 cm caudal to the former and is used for the surgical instruments. The 5 mm periosteal elevator is then introduced through the paraspinal muscles without any dissection till it is docked over the lamina then it is used to sweep the overlying soft tissues. Insertion of the endoscope and preparation of the surgical field. The endoscopic cannula and trochar are introduced through the first portal till they are docked over the superior lamina. The irrigation fluid is initiated and the trochar is removed to allow the blood to be washed out followed by an endoscope introduction through the cannula. The introducing abrader and the shaver were through the second portal and were then used to clean any remnants of soft tissue or muscles over the lamina and ligamentum flavum.

2. Laminotomy/medial facetectomy/ligamentum flavum removal: An angled curette is used to detach the superficial layer of the ligamentum flavum from the inferior edge of the superior lamina. A kerrison rongeour is used to perform a hemilaminotomy till the superior edge of the deep part of the ligamentum flavum is freed. Using the curette, the plane between the ligament and the dura is identified, ensuring that it is free from adhesions and the ligament is peeled down in a caudal direction. This is followed by the removal of the ligamentum flavum using the kerrison rongeour.

3. Nerve root identification/disc removal: After nerve root identification adjacent to the dural sac, the nerve root retracted medially. This allows for the discectomy to be conducted. If an annulotomy is required, it could be performed using a sheathed microknife. This is followed by a discectomy, the removal of any free fragments and foraminotomy if required.

4. Closure: The endoscope and instruments are removed, and any remaining fluid is discharged by manually squeezing the skin around each portal, followed by wound closure using a single stitch.

Intervention Type
Procedure/Surgery

Primary outcome measure
Perioperative data:
1. Length of operation time measured using medical records after surgery
2. Endoscopy irrigation amount measured using medical records after surgery
3. Estimated blood loss measured using medical records after surgery
4. Complications measured using video records of the endoscopy and clinical charts after surgery

Clinical outcomes are assessed at the time of discharge, and at 3, 6, and 12 months and followed by once per year postoperative until the end of this study:
1. Back pain and lower leg pain measured using a visual analog scale (VAS)
2. Functional recovery measured using the Oswestry Disability Index (ODI)
3. Overall treatment outcomes measured using the modified MacNab criteria

Secondary outcome measures
1. Hemoglobulin concentration in wash out measured using spectrophotometry according to the haemoglobincyanide method after surgery
2. Amount of bone harvested measured using collecting bone debris and calculated in volume by syringe cylinder after surgery
3. Accuracy of the pedicle screw placement measured using CT scanning after surgery
4. Fusion condition measured using CT scanning at 1 year and later follow-up after surgery
5. Cross-section area in decompression segment measured using CT and MRI scanning at 3 months follow-up after surgery
6. Irrigation pressure measured using a liquid manometer from a lumbal puncture set during surgery
7. Supplement in irrigation measured using medical records after surgery

Overall study start date
01/01/2020

Completion date
18/01/2031

Eligibility

Key inclusion criteria
1. Neurogenic symptoms induced by lumbar disk herniation
2. Computed tomography and/or magnetic resonance imaging indicating single level LDH, radiologic finding in accordance with clinical neural distribution
3. History of failed conservative treatment
4. Follow-up for at least 3 months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Lumbar instability, spondylolisthesis or deformity
2. Tumors, infections, or other lesions
3. Surgical history involving the corresponding segment
4. Delayed treated cauda equina syndrome or other irreversible neural deficits

Date of first enrolment
19/01/2021

Date of final enrolment
01/01/2030

Locations

Countries of recruitment
China

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Study participating centre
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Jishuitan Hospital

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/12/2031

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be stored in a non-publicly available repository (https://pan.baidu.com/). The data is available on request (tony_jxz@126.com) and will be published as a supplement to the publication of the results. The data are the intraoperative endoscopic video, and any form of private information of the patient is strictly confidential.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication