Comparative study of the efficacy and safety of minimally invasive interlaminar full-endoscopic discectomy versus conventional microscopic discectomy in single-level lumbar herniated intervertebral disc (ENDO-F Trial): A multicenter, prospective, randomized controlled trial protocol

Jin-Sung Kim
The Catholic University of Korea
Jun Ho Lee
Kyung Hee University Medical Center
Junseok Bae
Chungdam Wooridul Spine Hospital
Dong Chan Lee
Wiltse Memorial Hospital
Sang-Ha Shin
Chungdam Wooridul Spine Hospital
Han Joong Keum
Chungdam Wooridul Spine Hospital
Young Soo Choi
Chungdam Wooridul Spine Hospital
Sang Soo Eun
Chungdam Wooridul Spine Hospital
Seung Ho Shin
Wiltse Memorial Hospital
Hyun Jin Hong
Wiltse Memorial Hospital
Ji Yeon Kim
Wiltse Memorial Hospital
Tae Hyun Kim
Wiltse Memorial Hospital
Woojung Lim
The Catholic University of Korea
Junghoon Kim

The Catholic University of Korea
Sang-Min Park
Seoul National University College of Medicine and Seoul National University Bundang Hospital
Hyun-Jin Park
Hallym University College of Medicine
Hong-Jae Lee (kosailee73@gmail.com)
The Catholic University of Korea

Study protocol

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Abstract

Background

Advances in minimally invasive surgery have expanded the indications for interlaminar full-endoscopic discectomy. Although the clinical outcomes for this approach may be equivalent to those of conventional microscopic discectomy, the supporting evidence is based on small, single-center, prospective, and retrospective studies. Therefore, a multicenter, randomized controlled trial is warranted.

Methods

This will be a prospective, multicenter, randomized controlled trial comparing the efficacy and safety of interlaminar full-endoscopic discectomy to those of conventional microscopic discectomy. The trial will enroll 100 participants with a lumbar disc herniation, 50 in each group. The primary outcome will be the Oswestry Disability Index (ODI) score at 12 months post-surgery. Secondary outcomes will be: back and leg pain (visual analog scale); the ODI; the EuroQol-5-Dimension score; patient satisfaction; and walking distance/time and time to return to daily activities post-surgery. Surgical outcomes will include postoperative drainage, operative time, duration of hospital stay, postoperative creatine kinase level as an indicator of muscle injury, and postoperative scarring. Postoperative magnetic resonance imaging, computed tomography, and simple radiography will be performed to evaluate radiographic outcomes between the two surgical approaches. Surgery-related complications and adverse effects will be evaluated as safety outcomes. A single assessor at each participating hospital, blinded to group allocation, will assess the enrolled participants at baseline, 2 weeks and 3, 6, and 12 months postoperatively.

Discussion

This trial is designed to determine whether interlaminar full-endoscopic discectomy is clinically comparable to microscopic discectomy to treat lumbar disc herniations. All efforts will be made to reduce bias, including adequate sample sizes, blinded analyses, and multicenter prospective registration. The outcomes will inform practice, providing the evidence needed for the use of interlaminar full-endoscopic over microscopic discectomy by confirming the potential of this technique to improve patient satisfaction and clinical outcomes.

Trial registration

Clinical Research Information Service; cris.nih.go.kr. (KCT0006277); protocol version (v1, June 8, 2021)

Background

Discectomy is the most common surgical method for resolving lumbar radiculopathy caused by disc herniation and nerve root compression [1, 2]. Currently, microscopic discectomy is performed as a minimally invasive surgery, reducing the invasiveness of conventional open discectomy [3–5]. Minimally

invasive spinal surgery has been developed with the use of a tubular retractor, microscope, and endoscope to achieve effective neural decompression while preserving the stabilizing structures of the spine [4–7]. Although technically more demanding, interlaminar full-endoscopic discectomy has significantly reduced surgical invasiveness, thereby expanding the indications for endoscopic surgery [5, 8–10]. Specifically, interlaminar full-endoscopic discectomy offers several advantages over conventional microscopic discectomy, including a smaller skin incision, and thus, less scarring as well as less muscle damage, a lower infection rate and volume of blood loss, a less painful recovery, and a shorter hospital stay [3, 11–17]. Previous studies have reported that there are no differences in clinical outcomes between interlaminar endoscopic and microscopic discectomy [18–22]. However, the evidence regarding the advantages of interlaminar full-endoscopic discectomy is limited by the small number of patients included in these studies and the type of research design, namely retrospective, single-center prospective designs [7, 18–25]. Therefore, a multicenter, randomized controlled trial (RCT) is warranted.

To address this gap in evidence, we propose a multicenter, prospective RCT to compare the outcomes of interlaminar full-endoscopic versus microscopic discectomy. Our guiding hypothesis is that the efficacy and safety of interlaminar full-endoscopic discectomy and microscopic discectomy of the lumbar spine will be similar.

Methods/design

Trial design

This study aims to compare the outcomes of interlaminar full-endoscopic versus microscopic discectomy in a multicenter, assessor-blind, prospective RCT. Our methods have been approved by the institutional review boards of the participating hospitals (The Catholic University of Korea Seoul St Mary's Hospital; Kyung Hee University Medical Center; Chungdam Wooridul Spine Hospital; Wiltse Memorial Hospital; Seoul National University Bundang Hospital; Kangnam Sacred Heart Hospital; The Catholic University of Korea Daejeon St. Mary's Hospital).

Participant population

The study sample will be 100 adults, 20–80 years of age, who present with radiating pain in the lower extremities due to a lumbar disc herniation. The sample size calculation is provided below. Fifty participants will be allocated to each group: the interlaminar full-endoscopic group and microscopic discectomy groups. The equivalence between the two groups at baseline will be ascertained. Participants will be recruited from the five participating hospitals.

Inclusion criteria

The inclusion criteria are as follows: age, 20–80 years; diagnosis of single-level lumbar disc herniation; radiating pain to the lower extremities, with a pain score of > 4 on a 10-point visual analog scale (VAS); ability to follow instructions and to provide consent for participation; and willingness to comply with the trial’s follow-up protocol.

Exclusion criteria

The exclusion criteria are as follows: the presence of a spondylolisthesis (Meyerding grade ≥ II); history of lumbar spinal surgery at the same level; the presence of degenerative lumbar scoliosis (Cobb angle > 20°), other spinal diseases (e.g., ankylosing spondylitis, spine tumor, fracture, or neurologic disorders), and psychological disorders (e.g., dementia, intellectual disability, or drug abuse); and “any other” patient characteristic or disorders that the surgeons consider inappropriate for participation.

Recruitment

This is a multicenter prospective RCT, and each of the five participating hospitals will recruit trial participants from patients who decide to proceed with a one-level discectomy for lumbar disc herniation from June 2021 to December 2024; there will be no recruitment via the social media. The researchers from each of the five hospitals will screen potential participants to determine their eligibility. After providing informed consent, enrolled participants will undergo baseline assessments. The assessor will be blinded to the participants’ personal information.

Randomization and follow-up

After completing the baseline assessments, participants will be block-randomized into either the control (microscopy) or intervention (endoscopy) group, using a 1:1 allocation ratio, with a block size of four. The randomization list will be computer-generated and integrated into a web-based electronic case report form (eCRF) platform (iCReaT; internet-based clinical research and trial, icreat.nih.go.kr) accessible only to the trial’s authorized researchers. The randomization will be implemented independently at each participating hospital. Group allocation will be presented to the surgeons using consecutively numbered opaque envelopes. To evaluate the primary and secondary outcomes, follow-up assessments will be planned for each participant at 2 weeks and 3, 6, and 12 months after surgery. An independent researcher will perform the assessments at each time-point of follow-up, with phone interviews used under unavoidable circumstances in which in-person follow-up is not possible (Fig. 1).

Blinding

All the primary and secondary outcomes will be assessed at each participating hospital by a single assessor, who will be blinded to the group allocation. The surgeons and participants will know which procedure was performed (interlaminar full-endoscopic discectomy or microscopic discectomy); this information will not be revealed by either participants or surgeons to the assessor. If unblinding is required, based on the assessment findings, the assessor will be required to submit a justification to the trial team.

Surgical interventions

Active intervention: Interlaminar full-endoscopic discectomy

The technical procedure for interlaminar full-endoscopic discectomy [26], including recent updates, is well described in the literature [3, 4, 27–31]. This surgical approach is familiar to spine surgeons, being similar to the conventional posterior approach with the exception of having to create a working channel for the endoscope and spinal instrument [3, 4, 30]. The procedure is performed under general or spinal anesthesia with the participant placed prone. The surgical table is bent approximately at the level of the lower lumbar spine, with appropriate flexion of the hip and knees; this position widens the interlaminar window [3, 4]. A 5–7 mm skin incision is created at the working channel's entry point, approximately 1 cm from the midline at the level of the symptomatic herniated disc, visualized by intraoperative C-arm anteroposterior fluoroscopy imaging, as previously described [28]. The working channel is inserted and positioned at the target point over the ligamentum flavum with sufficient subdermal fascia dissection. After optimal positioning of the working channel at the targeted location, the endoscope is inserted into the working channel under sufficient irrigation with saline solution. [3, 4, 28, 30, 31].

Surgery is performed by inserting the required spinal surgical instruments (bipolar radiofrequency cauterization devices, burrs, Kerrison punches, and pituitary rongeurs) through the working channel. The paravertebral muscle is coagulated to identify the border of the interlaminar window [3, 4, 28]. The ligamentum flavum is resected using a punch or split using a probe at the level of the tip of the descending facet [3, 11, 28, 29]. The discectomy is performed in a fully endoscopic, minimally invasive manner (Fig. 2).

Control intervention: Conventional microscopic discectomy

For microscopic discectomy, the target lumbar level of symptomatic disc herniation is again visualized under C-arm intraoperative fluoroscopy, and a 2.5 cm midline incision is made over the target level. The paraspinal muscle is detached from the spinous process and the lamina, and detached muscle towing is performed in a minimally invasive fashion through the small skin incision under microscopic visualization. Minimal laminotomy is then performed using a burr and Kerrison punches under microscopic visualization. After the partial removal of the ligamentum flavum under the lamina, discal impingement of the spinal roots and dura is verified. The spinal nerve root is retracted using a root retractor, and the herniated disc is removed by pituitary forceps below the retracted nerve root. Following discectomy, the surgical field is verified for any remnant disc, with the procedure then completed.

Measured outcomes

A complete description of the time-points at which the data on the primary and secondary outcomes will be collected is provided in Table 1.

Table 1
Evaluation schedule

Visit type	Screening	Surgical intervention	Follow-up			
Visit	1	2	3	4	5	6
Visit week	4–0 weeks	0–2 days	2 weeks	12 weeks	24 weeks	52 weeks
			± 5 days	± 4 weeks	± 8 weeks	± 8 weeks
Informed consent	■					
Demographics*	■					
Inclusion/Exclusion	■					
Randomization		■				
Surgery		■				
MRI (or CT)†	■	■				
Simple radiographs	■		■	■	■	■
ODI	■		■	■	■	■
EQ-5D-5L	■		■	■	■	■
VAS	■		■	■	■	■
POSAS				■	■	■
Other survey‡			■	■	■	■
Adverse events		■	■	■	■	■

POSAS, Patient and Observer Scar Assessment Scale; *, baseline patient characteristics, including past medical/surgical history, physical examination, and laboratory tests; †, CT imaging used when MRI cannot be performed; ‡, including surgery satisfaction, walking time/distance, and return to daily activities after surgery.

Primary outcome

The primary outcome will be the efficacy of the surgical intervention (interlaminar full-endoscopic discectomy or conventional microscopic discectomy), measured using the Oswestry Disability Index (ODI) score at 12 months [32, 33]. The ODI is the most useful tool for evaluating patient-reported functional outcome for lumbar spinal disabilities in a clinical setting [32, 33]. The ODI evaluates the level of function on activities of daily living for patients with low back pain across the following 10 areas: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling. Each section of the ODI is scored on a 5-point scale, with a score of 5 representing the most severe disability.

The total ODI score was used for analysis, calculated as the sum of the scores across the 10 areas divided by the total possible score, and expressed as a percentage (i.e., multiplied by 100). For all unanswered questions, the total possible score is reduced by five. If the participant checks more than one answer, the highest score is recorded. The ODI will be administered and scored by the assessor and recorded in the eCRF system.

Secondary outcomes

The following secondary outcomes will be included in the analysis: patient-reported outcomes, clinical outcomes, radiographic outcomes, and adverse events. Patient-reported outcomes are as follows: (1) presence and severity of low back pain and pain radiating to the lower-extremities, measured using a 10-point VAS score, ranging from “0” (no pain) to “10” (severe pain); (2) quality of life (QOL), measured using the EuroQol-5-dimension-5-level (EQ-5D-5L) questionnaire, which consists of five questions, with the total score ranging between “0” and “1,” with a higher score indicating a better QOL [34]; (3) satisfaction with the surgery; and (4) walking distance/time and time to return to daily activities after surgery. The following clinical outcomes will be measured: (1) postoperative surgical scarring, measured using the Patient and Observer Scar Assessment Scale (POSAS; version 2.0), which consists of six items scored on a 10-point system, with a score of “6” (i.e., a score of ‘1’ on each item) indicative of normal skin and a score of “60” (i.e., a score of “10” on each item) indicative of the “worst scar imaginable” and (2) surgery-related variables, namely postoperative drainage (mL), operative time (min), duration of hospitalization (h), and postoperative creatine kinase. The following radiographic outcomes will be obtained: (1) the extent of disc removed and injury to the facet joint, measured using postoperative magnetic resonance (MR) or computed tomography (CT) images and (2) simple radiographs will be used for measuring other complications during the follow-up period. Safety will be evaluated based on the number of adverse events and the severity of these events, as well as surgery-related events. Adverse events will be reported to the surgeon by the participant or assessor and recorded in the electronic database.

Radiographs will be obtained in the anteroposterior, lateral, flexion, and extension views. Spondylolisthesis and segmental instability at the target surgical level will be scored based on these images. Radiographs will be obtained at baseline and at each of the follow-up time-points. Preoperative spinal MR imaging will be systematically conducted in the sagittal and axial planes to determine the type and location of the disc herniation.

The data on patient-reported outcomes, clinical outcomes, plain radiographs, and adverse events will be collected at baseline and at each follow-up time-point (2 weeks and 3, 6, and 12 months after surgery). Outcomes will be managed and evaluated by the assessor and recorded in the eCRF system (Table 1).

Statistical analysis

All statistical analyses will be performed using SAS Enterprise Guide 4 (SAS Institute Inc., Cary, North Carolina, USA). The equivalence of baseline variables in both groups will be confirmed statistically prior to the main comparative statistical analyses.

Modified intention-to-treat (mITT) analysis will be performed, and detailed methods for reducing selection bias due to crossover and loss to follow-up will be used. The mITT strategy will be applied in this RCT, with participants entered in the analysis if they underwent a randomly assigned surgery, thus avoiding the effects of crossover and dropouts, which could break the random assignment to the treatment groups. Participants excluded before or after surgery will not be entered into the analysis or replaced, thus avoiding the risk of bias in allocation concealment. The primary outcome (the ODI score at 12 months post-surgery) will be compared between the two groups. Interlaminar full-endoscopic discectomy will be considered to be equivalent to microscopic discectomy concerning surgical outcomes if the 95% confidence interval (CI) of the treatment difference value of the Interlaminar full-endoscopic discectomy group is included in the equivalence limit of 12.8 points

To analyze the time-dependent change in secondary patient-reported and clinical outcomes (i.e., VAS pain scores for the back and lower extremities and ODI, EQ-5D, and POSAS scores), a linear mixed model repeated-measures analysis of variance will be used. Time will be regarded as a categorical variable (2 weeks and 3, 6, and 12 months) and analyzed to evaluate serial changes from baseline, within each group, and between the two groups at each time-point, with a posthoc test used for any significant time- and group-differences identified.

Chi-squared test for categorical variables and Student's t-test for continuous variables will be used for the analyses of other clinical and radiographic outcomes and adverse effects between the two groups. The collected data's distribution will be evaluated using the Shapiro-Wilk test, with a two-sided P-value. Normally distributed continuous variables will be reported as mean and standard deviation (SD), with non-normally distributed continuous variables reported as median and interquartile range. Categorical variables will be reported as count and percentage (%).

Data management

Participant data will be anonymized and entered into the iCReaT platform created by the Korean government to allow researchers and investigators to input the research data safely and directly. The iCReaT platform is equipped with a web-based encryption system to protect the research data from unauthorized access and disclosure, and it will be accessible only to the principal investigator and designated statistical analysts. The e-CRF system will be used for this clinical trial. The iCReaT will be managed by specialized clinical research coordinators in each hospital and via a contract with a specialized company with extensive experience in eCRF management. Regarding the monitoring of this clinical trial, both on-site monitoring and in-house monitoring using the electronic data capture system will be conducted by designated monitoring researchers.

Sample size justification

In this trial, 100 participants will be recruited, with 50 in each group. According to a previous report, the minimal clinically important ODI difference is 12.8 points, with an SD value of 17.1 points at 1-year after endoscopic discectomy [14, 20]. Based on the equivalence limit of 12.8, 50 participants are required in each group, with an alpha value of 0.05, a power of 0.90, a two-sided 95% CI, and a loss to follow-up of

20%. Power Analysis and Sample Size software (version 15; NCSS, Kaysville, UT, USA) were used to calculate the sample size.

Discussion

Previous studies have reported that interlaminar full-endoscopic discectomy has similar clinical outcomes and less invasiveness as open microscopic discectomy [18–22]. However, evidence of the advantages of interlaminar full-endoscopic discectomy is limited by the type of research design previously applied, i.e., retrospective, single-center prospective designs [7, 18–25].

This trial will be the most valuable, multicenter, prospective RCT to evaluate and comparatively analyze the efficacy, safety, and applicability of interlaminar full-endoscopic discectomy, compared with open discectomy, in patients with lumbar disc herniation. The quality of the evidence will be improved by an adequate sample size, blinded assessments, and prospective registration from multiple centers to reduce bias; this will ensure that the two approaches are evaluated in an equivalent manner. We anticipate that this high-quality evidence will provide a clear conclusion on the efficacy and safety of interlaminar full-endoscopic discectomy as an alternative option, with the same surgical outcome and less invasiveness, for the treatment of lumbar disc herniation.

Abbreviations

CI
confidence interval
CT
computed tomography
eCRF
electronic case report file
EQ-5D-5L
EuroQol 5 Dimension 5 level
iCReaT
internet-based clinical research and trial
mITT
modified intention-to-treat
MR
magnetic resonance
ODI
Oswestry Disability Index
POSAS
Patient and Observer Scar Assessment Scale
QOL
quality of life

RCT
randomized controlled trial
SD
standard deviation
VAS
visual analog scale

Declarations

Ethics approval and consent to participate*:* The design and protocol of this multicenter, assessor-blinded, prospective RCT have been approved by the institutional review board of the five participating hospitals (Catholic University of Korea, Daejeon St Mary's Hospital, DC21ENDOI0021; Catholic University of Korea Seoul St Mary's Hospital, KC21ENDOI0469; Kyung Hee University Medical Center, KHUH 2021; Chungdam Wooridul Spine Hospital, 2021-07-WSH-008; and Wiltse Memorial Hospital, 2021-W03). All participants meeting our eligibility criteria will be required to provide informed consent for the surgery and for the use of their data in research prior to enrollment and randomization.

Consent for publication*:* Not applicable.

Availability of data and materials*:* The electronic database server (iCReaT) will not be publicly accessible. Access to the data set is provided only to the Data Management Committee of the Korean Government Research Consortium. The study findings will be published in a peer-reviewed journal.

Competing interests*:* Jin-Sung Kim is a consultant for RIWOSpine, GmbH, Germany, Stöckli Medical AG, Switzerland and Elliquence, LLC, USA. Jun Ho Lee is a consultant for RIWOSpine, GmbH, Germany. Junseok Bae is a consultant for Joimax, GmbH, Germany. The other authors declare that they have no competing interests.

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Authors' contributions*:*K-JS, L-JH, B-JS, L-DC, P-SM, P-HJ, and L-HJ contributed to the conceptualization, design, writing, and editing of the study protocol. S-SH, K-HJ, C-YS, E-SS, S-SH, H-HJ, K-JY, K-TH, L-W, and K-J contributed to the surgical procedure and data collection. All authors approved the final manuscript.

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Figures

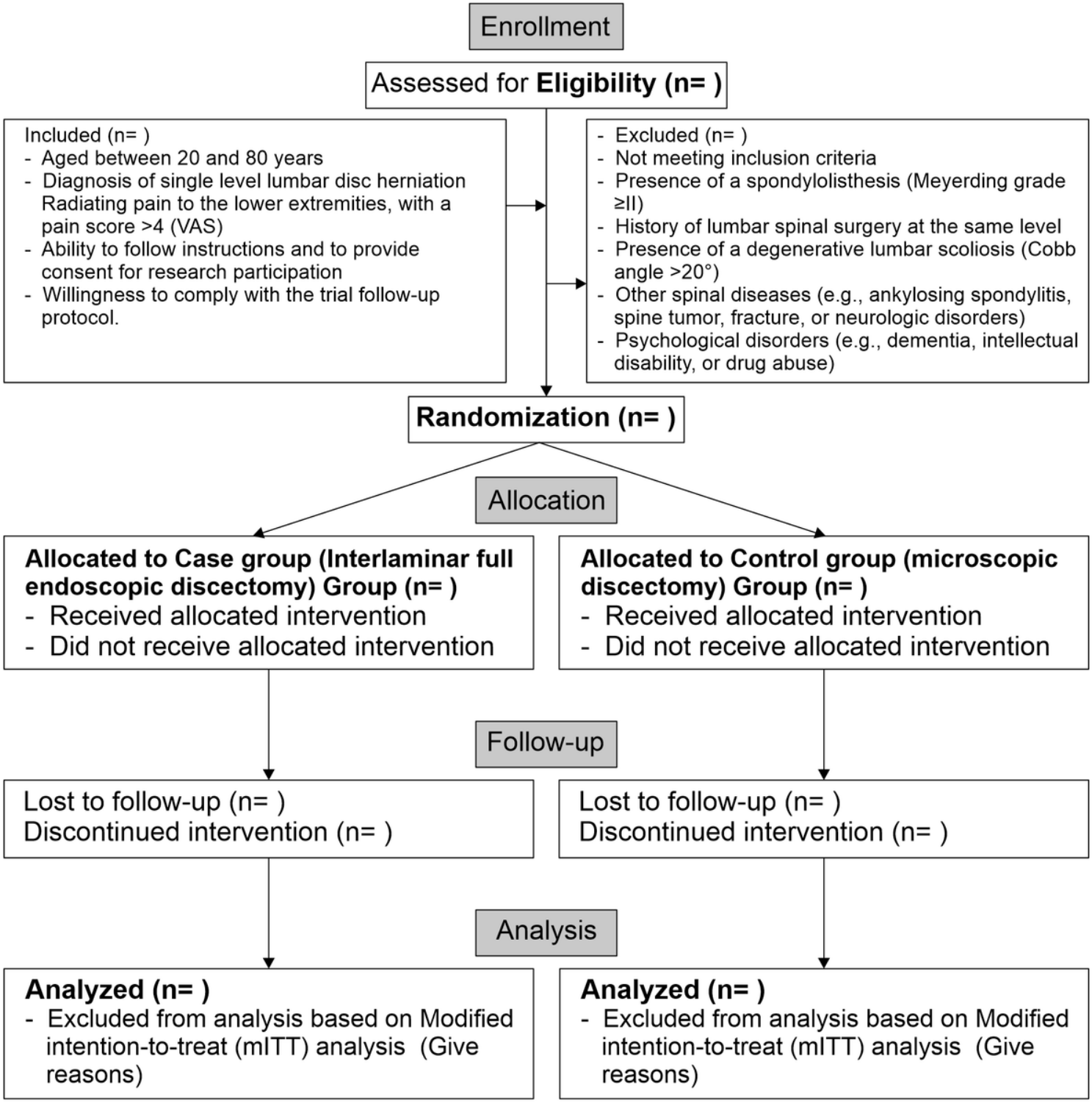

Figure 1

CONSORT study flow diagram for the trial protocol.

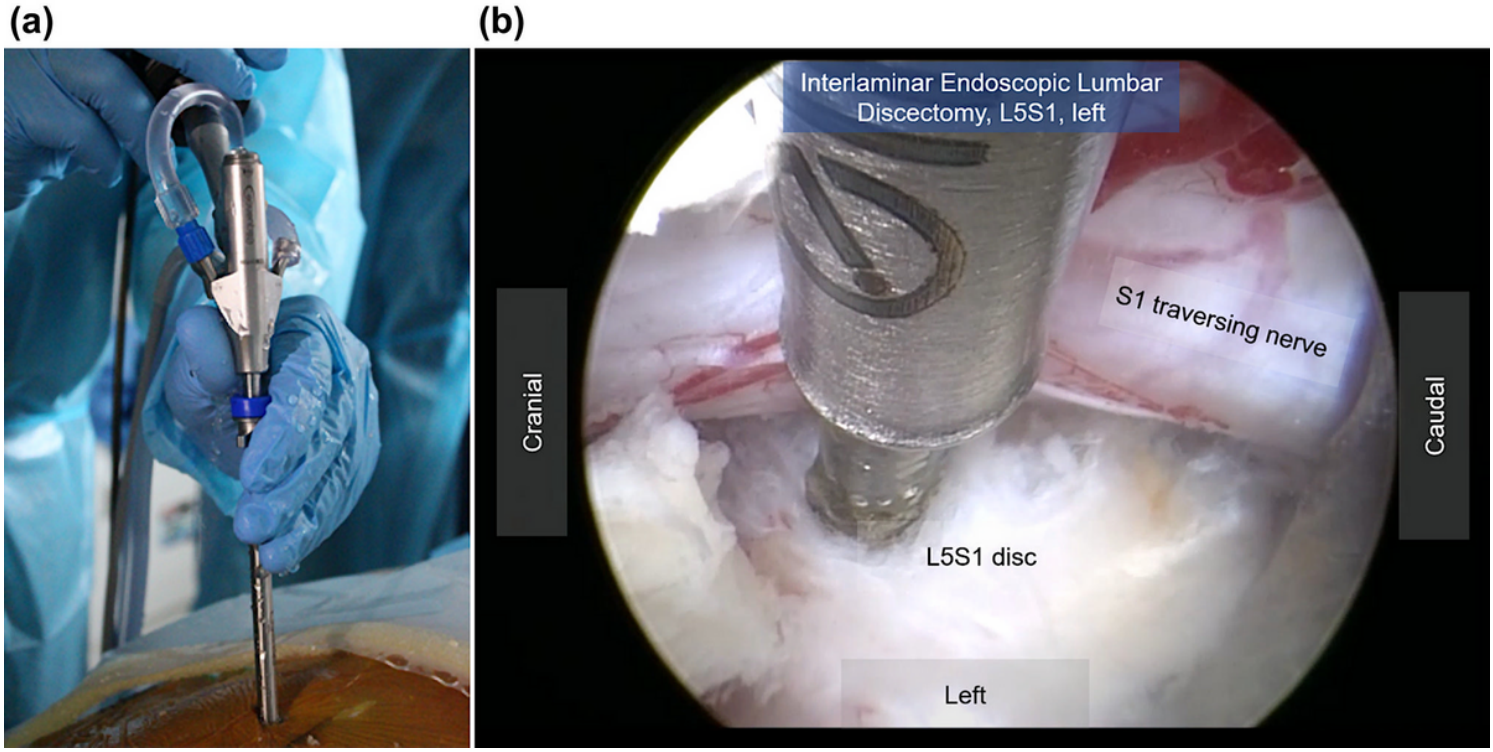

Figure 2

(a) Operative field of interlaminar full-endoscopic discectomy. (b) Intraoperative endoscopic view, showing the disc space and decompressed left S1 nerve root.