Biportal Endoscopic Discectomy Versus Microdiscectomy: RCT, Non-inferiority Trial

CLINICALTRIALS.GOV IDENTIFIER: NCT03924700

STUDY DESCRIPTION

Brief Summary

This study is to compare the clinical outcome between the biportal endoscopic discectomy and microdiscectomy in herniated intervertebral disc of lumbar spine.

Condition or Disease: Lumbar Herniated Intervertebral Disc

Intervention/treatment:

- Procedure: Biportal endoscopy
- Procedure: Microdiscectomy

Phase: Not Applicable

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment: 64 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Single (Outcomes Assessor)

Primary Purpose: Treatment

Official Title: Biportal Endoscopic Discectomy Versus Microdiscectomy: RCT, Non-inferiority Trial

Actual Study Start Date: April 2019

Actual Primary Completion Date: November 2021

Actual Study Completion Date: December 2021

ARMS AND INTERVENTIONS

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OUTCOME MEASURES

Primary Outcome Measures:

1. Oswestry disability index (ODI) [ Time Frame: at 1 year after surgery ]

   The ODI is based on a self-administered questionnaire measuring “back-specific function.” The questionnaire comprises 10 items, each with 6 levels of response. Each item is scored from 0 to 5, and the total summation is converted to a 0-100 scale. The ODI scores range from 0 to 100, with higher scores indicating severe symptoms. This is assessed by ODI survey at 1 year after surgery.

   1. Change from baseline Oswestry disability index (ODI) [ Time Frame: 3, 6, and 12, months, and every year, up to 5 year after operation ]

   The ODI is based on a self-administered questionnaire measuring “back-specific function.” The questionnaire comprises 10 items, each with 6 levels of response. Each item is scored from 0 to 5, and the total summation is converted to a 0-100 scale. The ODI scores range from 0 to 100, with higher scores indicating severe symptoms.

   2. Change from baseline Visual Analog Pain Scale (VAS) [ Time Frame: 4, 8, 12, 48 hours, 2 weeks, 3, 6, and 12, months, and every year, up to 5 year after operation ]

   VAS is a measurement score that indicates pain severity status. VAS score comprised a 10-cm line with “none” (0) on one end of the scale and “disabling pain” (10) on the other.

   3. Change from baseline EuroQol-5 dimension (EQ-5D) value [ Time Frame: 3, 6, and 12, months, and every year, up to 5 year after operation ]

   EQ-5D is a standardized instrument developed by the EuroQol Group as a measure of health-related quality of life that can be used in a wide range of health conditions and treatments. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Rated level can be coded as a number 1 to 5, which indicates having no problems for 1, and having extreme problems for 5. As a result, a person's health status can be defined by a 5-digit number, ranging from 11111 (having no problems in all dimensions) to 55555 (having extreme problems in all dimensions). EQ-5D health states may be converted into a single index value. The index values are a major feature of the EQ-5D instrument, facilitating the calculation of quality-adjusted life years (QALYs) that are used to inform economic evaluations of health care interventions. The value sets are anchored on 11111 = 1 and 55555 = 0 and can therefore be used in QALY calculations.

   4. Change from baseline PainDETECT score [ Time Frame: 3, 6, and 12, months, and every year, up to 5 year after operation ]

   The PainDETECT Questionnaire (PDQ) is a screening tool designed to detect neuropathic pain in patients with chronic low back pain (LBP) based on self-reported pain characteristics. The degree of the seven types of pain quality, the type of pain pattern, and the presence of radiating pain. From the three components of the PDQ, a total score is calculated; a high score indicates that the pain is likely to have a neuropathic component. Scoring is performed using a scoring manual, and results in a final screening score: a score of 0-12 indicates nociceptive pain, 19-38 indicates neuropathic pain, and 13-18 indicates mixed pain.
5. Number of participants with treatment-related adverse events as assessed by CTCAE v4.0 [Time Frame: up to 1 month after operation]
   Surgery related adverse events (incidental durotomy, wound infection, re-operation, re-admission)
6. Operation duration time (minutes) [Time Frame: Immediate after operation]
   Intraoperative time in minutes
7. Volume of postoperative drainage (ml) [Time Frame: Within 3 days after operation]
   Total drainage after surgery in milli-liter
8. Number of participants with complete discectomy [Time Frame: Within 3 days after operation]
   After surgery, degree of discectomy was measured using postoperative MRI
9. Concentration of creatine phosphokinase level in blood [Time Frame: At 2 day after surgery]
   Creative phosphokinase assessment to measure muscle injury at operation
10. Volume of postoperative Fentanyl consumption [Time Frame: At 3 days after operation]
    Total amount of fentanyl consumption after surgery (PCA dose + rescue dose)
11. Times of hospital stay (hours) [Time Frame: Within 7 days after operation]
    Total hospital stay after surgery
12. Number of radiographic complications [Time Frame: every year, up to 5 year after operation]
    Radiographic complications includes disc degeneration, facet degeneration, re-ruptured disc, back muscle atrophy, kyphotic change, disc rupture...

ELIGIBILITY CRITERIA

Ages Eligible for Study: 20 to 80 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- patients aged between 20 and 80 who has radiating pain (VAS >=40) on lower extremities with HIVD patients who required one-level discectomy between L1 and S1 those who (only if a signature was obtainable), or whose legal guardian, fully understood the clinical trial details and signed the informed consent form

Exclusion Criteria:
- Revision surgery Over spondylolisthesis Gr II Degenerative lumbar scoliosis (Cobb angle >20) patients with a history of other spinal diseases (compression fracture, spondylitis, tumor) women with positive pregnancy tests before the trial or who planned to become pregnant within the following 3 years patients with a history of malignant tumor or malignant diseases (but the cases of cured disease with no relapse for the past 5 years were included in the present study) patients with mental retardation or whose parents or legal guardians were older or had mental disabilities other patients viewed as inappropriate by the staff

CONTACTS AND LOCATIONS

Contacts

Locations

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Korea, Republic of, Chungnam National University Hospital Daejeon

Sponsors and Collaborators

Seoul National University Hospital

MORE INFORMATION

Responsible Party: Seoul National University Hospital

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Other Study ID Numbers: BESS_002

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Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Seoul National University Hospital:
- Herniated intervertebral disc
- Discectomy Microscope
- Biportal endoscopy

Additional relevant MeSH terms:
- Bone Diseases
- Musculoskeletal Diseases
- Hernia
- Pathological Conditions, Anatomical
- Intervertebral Disc Displacement
- Spinal Diseases