Posture control after lumbar microdiscectomy

Submission date	Recruitment status	Prospectively registered
17/02/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
10/03/2008	Completed	☐ Results
Last Edited	Condition category	Individual participant data
10/03/2008	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 550782

Study information

Scientific Title

Posture control after lumbar microdiscectomy: effect of transmuscular surgical approach and of early postoperative physiotherapy - a randomised clinical trial

Study objectives

- 1. Transmuscular surgical approach causes less damage to postoperative posture control because it does not damage the back muscle insertions
- 2. Early postoperative physiotherapy improves short and long term posture control

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Commissie Medische Ethiek of Leuven University Hospitals in November 2007.

Study design

Interventional, randomised, single centre trial with four arms (two variables: early specific physio versus later non-specific physio; transmuscular versus paramedian surgical approach).

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sciatica caused by a lumbar disc herniation

Interventions

- 1. Transmuscular surgical approach versus classic paramedian approach to the disc herniation at surgery
- 2. Early postoperative physiotherapy, starting two weeks postoperatively, and consisting of an individualised program with standardised goals versus 'conservative' treatment: no physiotherapy in the first six weeks post-operation and after six weeks only when indicated

Follow up is one year for all four arms.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Muscle control (assessed by postural balance test and sit-to-stand test), assessed in the lab at two weeks, eight weeks and six months post-operatively.

Key secondary outcome(s))

Comfort:

- 1. Back pain
- 2. Sciatica
- 3. Functional status
- 4. Return to work

Secondary outcome measures are assessed by standardised patient questionnaires preoperatively and at two weeks, eight weeks, six months and one year postoperatively.

Completion date

31/12/2009

Eligibility

Key inclusion criteria

- 1. One level disc herniation, either L4-L5 or L5-S1, explaining symptoms and representing operative indication. Purely median disc herniations are excluded.
- 2. Age: 18 60 years, either sex
- 3. Living within 30 km perimeter of the hospital
- 4. Informed consent signed

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Emergency operation required
- 2. Litigation, worker's compensation
- 3. Clinical suspicion of depression or fibromyalgia (the suffering is not exlusively explained by the disc herniation)
- 4. Previous lumbar surgery, irrespective of the level
- 5. Significant neurological deficit (weakness worse than 4/5)
- 6. Systemic disease significantly affecting patient's functioning (American Society of Anaesthesiologists [ASA] grade greater than 3)
- 7. Median disc herniation
- 8. Patient unable to communicate in the Dutch language

Date of first enrolment

18/02/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Belgium

Study participating centre Department of Neurosurgery

Leuven Belgium 3000

Sponsor information

Organisation

University Hospitals Leuven (The Netherlands)

ROR

https://ror.org/0424bsv16

Funder(s)

Funder type

Industry

Funder Name

Contribution for logistic expenses:

Funder Name

Medtronic B.V. (The Netherlands)

Funder Name

Stryker Nederland (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes