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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

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Additional identifiers

Protocol serial number
S50782

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.

Primary study design
Interventional

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).

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