

# Posture control after lumbar microdiscectomy

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Bart Depreitere

### Contact details

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3000

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

### **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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet (in Dutch).

### **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 measure**

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.

### **Secondary outcome measures**

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.

### **Overall study start date**

18/02/2008

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

100

### **Key exclusion criteria**

1. Emergency operation required
2. Litigation, worker's compensation
3. Clinical suspicion of depression or fibromyalgia (the suffering is not exclusively 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)

**Sponsor details**

Herestraat 49

Leuven

Belgium

3000

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uzleuven.be/>

**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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration