

# 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

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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.

### **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 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)

### 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