

# The Sciatica-PLDD trial: a prospective randomised controlled efficiency and efficacy trial on percutaneous laser disc decompression as a treatment modality for sciatica caused by a lumbar disc herniation

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/07/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<http://www.pldd.nl>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

P04.042; NTR219

## **Study information**

### **Scientific Title**

The Sciatica-PLDD trial: a prospective randomised controlled efficiency and efficacy trial on percutaneous laser disc decompression as a treatment modality for sciatica caused by a lumbar disc herniation

### **Study objectives**

Percutaneous laser disc decompression (PLDD) is more cost-effective than conventional surgical treatment for lumbar disc herniation and allows faster patient rehabilitation, while long-term functional results are comparable.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the local medical ethics committee

### **Study design**

Multicentre, randomised, active controlled, parallel group trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

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

Hospital

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

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Sciatica

### **Interventions**

Patients who fit the inclusion and exclusion criteria for the trial for lumbar disc herniation will be randomised into two groups:

1. The first group will receive microsurgical discectomy in their own hospital
2. The second group will be referred to 1 of 4 assigned PLDD-centers, where percutaneous laser disc decompression will be carried out by an experienced interventional (neuro-)radiologist

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Roland Disability Questionnaire for Sciatica

**Secondary outcome measures**

1. A cost-effectiveness-analysis will be carried out on the basis of health-related utility factors. This will include costs of sickness absence and long-term disability.
2. Neurological and radiological parameters

**Overall study start date**

01/11/2004

**Completion date**

31/12/2006

**Eligibility****Key inclusion criteria**

1. Patient aged 18 - 70 years
2. At least 8 weeks of persisting sciatic pain with or without paresis or sensory impairment
3. Patients must qualify for surgical intervention
4. Clear unilateral lumbar disc herniation on computed tomography (CT) or magnetic resonance imaging (MRI) with a anteroposterior diameter less than 33% of the spinal canal
5. Informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

330

**Total final enrolment**

**Key exclusion criteria**

1. Previous discectomy at the same level
2. Cauda equina syndrome
3. Lytic or degenerative spondylolisthesis
4. Spinal/lateral recess stenosis
5. Intervertebral disc space of less than 7 mm
6. Signs of sequestration
7. Pregnancy
8. Serious co-morbidity, either somatic or psychiatric
9. Emigration in the near future
10. No or insufficient knowledge of the Dutch language

**Date of first enrolment**

01/11/2004

**Date of final enrolment**

31/12/2006

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Leiden University Medical Center

Leiden

Netherlands

2300 RC

## Sponsor information

**Organisation**

Leiden University Medical Centre (LUMC) (Netherlands)

**Sponsor details**

Albinusdreef 2

P.O. Box 9600

Leiden

Netherlands

2300 RC

**Sponsor type**

University/education

**Website**

<http://www.lumc.nl/>

**ROR**

<https://ror.org/027bh9e22>

## Funder(s)

**Funder type**

Government

**Funder Name**

The Dutch Health Care Insurance Board (CVZ) (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	13/05/2009		Yes	No
<a href="#">Results article</a>	results	01/05/2015	10/07/2019	Yes	No
<a href="#">Results article</a>	results	01/06/2017	10/07/2019	Yes	No