

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

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

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
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

Study type(s)

Treatment

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(s)

Roland Disability Questionnaire for Sciatica

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

115

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)

ROR

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

Funder(s)

Funder type

Government

Funder Name

The Dutch Health Care Insurance Board (CVZ) (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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/05/2015 | 10/07/2019 | Yes | No |
| Results article | results | 01/06/2017 | 10/07/2019 | Yes | No |

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|----------------------------------|---------------|------------|------------|-----|-----|
| Protocol article | protocol | 13/05/2009 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |