

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

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

Contact name

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Contact details

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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

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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?
Protocol article	protocol	13/05/2009		Yes	No
Results article	results	01/05/2015	10/07/2019	Yes	No
Results article	results	01/06/2017	10/07/2019	Yes	No