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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
10/07/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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