The Sciatica-PLDD trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25415

Source
NTR

Brief title
N/A

Health condition

Sciatica caused by lumbar disc herniation

Sponsors and support

Primary sponsor: The Dutch Health Care Insurance Board
Postbus 320
Diemen
1110 AH
Netherlands

Intervention

Outcome measures

Primary outcome

Roland Disability Questionnaire for Sciatica.

Secondary outcome

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.
Neurological and radiological parameters will also be assessed.

Study description

Background summary

The Sciatica-PLDD trial is a prospective randomized controlled trial. Patients who fit the in- and exclusion criteria for the trial for lumbar disc herniation will be randomised into twogroups.
- The first group will receive microsurgical discectomy in their own hospital.

- The second group will be referred to 1 of 4 assigned PLDD-centers, where Percutaneous Laser Discus Decompression will be carried out by an experienced interventional (neuro)radiologist.

Patients in both groups will be treated within 4 weeks after randomisation. Follow up visits for both groups will take place in the referring hospital 4, 8, 26 and 52 weeks after treatment.
- Patient evaluation will consist of careful history taking and standardized physical examination by well trained, experienced research nurses. Additionally, patients will be asked to fill out questionnaires 2, 6, 12, 38, 78 en 104 weeks after treatment.

- The primary outcome measure is functional improvement. This will be assessed using the Roland Questionnaire for Sciatica. Moreover, 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. Neurological and radiological parameters will also be assessed.

Study objective

Percutaneous Laser Disc Decompression is more cost-effective than conventional surgical treatment for lumbar disc herniation and allows faster patient rehabilitation, while long-term functional results are comparable.

Study design

N/A

Intervention

Patients who fit the in- 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 Discus Decompression will be carried out by an experienced interventional (neuro)radiologist.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient age 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 CT- or MRI imaging with a anteroposterior diameter less than 33% of the spinal canal;

5. Informed consent.

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 < 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2004
Enrollment:	330

Type: Actual

Ethics review

Positive opinion
Date: 05-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL182
NTR-old	NTR219
Other	: P04.042
ISRCTN	ISRCTN25884790

Study results

Summary results
N/A