The Sciatica-PLDD trial.

Gepubliceerd: 05-09-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25415

Bron
NTR

Verkorte titel
N/A

Aandoening

Sciatica caused by lumbar disc herniation

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Roland Disability Questionnaire for Sciatica.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2004

Aantal proefpersonen:	330
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A