

A multicenter double blind randomised clinical cost-effectiveness trial. Microendoscopic lumbar discectomy versus conventional microsurgery. Blind for patient and research-nurse.

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|--------------------------|-----------------------------|--|
| Submission date | Recruitment status | <input checked="" type="checkbox"/> Prospectively registered |
| 16/07/2004 | No longer recruiting | <input checked="" type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 08/09/2004 | Completed | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 30/05/2017 | Nervous System Diseases | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A multicenter double blind randomised clinical cost-effectiveness trial. Microendoscopic lumbar discectomy versus conventional microsurgery. Blind for patient and research-nurse.

Acronym

Sciatica-MED-trial

Study objectives

Severe sciatica caused by a lumbar disc herniation with root compression and indication for surgery based on clinical picture and Magnetic Resonance Imaging (MRI).

Microendoscopic discectomy (MED) is more (cost)-effective than open discectomy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicenter randomised double-blind clinical cost-effectiveness trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sciatica

Interventions

Randomisation in operation room to:

1. Microendoscopic surgery
2. Conventional microsurgery

Intervention Type

Procedure/Surgery

Primary outcome(s)

Roland Disability Questionnaire for Sciatica (RDQ)

Key secondary outcome(s)

1. Perceived recovery
2. Visual analog scale (VAS)
3. VAS of back pain and combined leg and back pain
4. McGill pain questionnaire
5. Short-Form-36 questionnaire (SF 36)

6. Sciatica frequency and bothersome index (SFB)

7. Prolo scale

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Patients (18-70 years) with at least 8 weeks sciatica not reacting to conservative treatment. An indication for surgery is made by the clinical picture with MRI confirmation of a lumbar disc herniation.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center

Leiden

Netherlands
2333 ZA

Sponsor information

Organisation

Dutch Health Care Insurance Board (College voor Zorgverzekeringen [CVZ]) (Netherlands)

Funder(s)

Funder type

Government

Funder Name

College voor Zorgverzekeringen

Alternative Name(s)

Health Care Insurance Board, Netherlands, CVZ

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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 | 08/07/2009 | | Yes | No |
| Results article | results | 01/10/2011 | | Yes | No |

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|--|-------------------------------|------------|------------|----|
| <u>Results article</u> | long-term results | 01/12/2017 | Yes | No |
| <u>Protocol article</u> | protocol | 13/05/2006 | Yes | No |
| <u>Other publications</u> | subgroup analysis | 01/11/2010 | Yes | No |
| <u>Participant information sheet</u> | Participant information sheet | 11/11/2025 | 11/11/2025 | No |