

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

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

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

Results article	long-term results	01/12/2017	Yes	No
Protocol article	protocol	13/05/2006	Yes	No
Other publications	subgroup analysis	01/11/2010	Yes	No