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

Submission date	Recruitment status
16/07/2004	No longer recruiting
Registration date 08/09/2004	Overall study status Completed
Last Edited	Condition category
30/05/2017	Nervous System Diseases

- [X] 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Roland Disability Questionnaire for Sciatica (RDQ)

Secondary outcome measures

- 1. Perceived recovery
- 2. Visual anolog 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

Overall study start date

01/01/2006

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

Age group Adult

Lower age limit 18 Years

Upper age limit 70 Years

Sex Both

Target number of participants 150

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)

Sponsor details

Postbus 320 Diemen Netherlands 1110AH +31 (0)207978555 info@cvz.nl

Sponsor type Government

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	13/05/2006		Yes	No
Results article	results	08/07/2009		Yes	No
Other publications	subgroup analysis	01/11/2010		Yes	No
Results article	results	01/10/2011		Yes	No
<u>Results article</u>	long-term results	01/12/2017		Yes	No