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

Submission date	Recruitment status	[X] Prospectively registered
16/07/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

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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
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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
Results article	long-term results	01/12/2017		Yes	No