Minimally Invasive Surgery versus Open Surgery (MISOS) in the treatment of spondylolisthesis; a randomised controlled trial.

Published: 15-08-2014
Last updated: 21-04-2024

To document whether patients treated with minimally invasive surgery experience less back pain at 2 and 6 weeks after surgery, compared to patients treated with conventional open instrumented surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON50599

Source
ToetsingOnline

Brief title
MISOS trial

Condition

- Bone disorders (excl congenital and fractures)
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
spondylolisthesis, vertebral slippage

Research involving
Human

Sponsors and support

Primary sponsor: neurochirurgie
Source(s) of monetary or material Support: Biomet

Intervention

Keyword: lumbar fusion, minimally invasive surgery, spine surgery, spondylolisthesis

Outcome measures

Primary outcome

Score on the Visual Analoge Scale (VAS) for low back pain (ranging from 0 - 100

mm) at 2 and 6 weeks after surgery.

Secondary outcome

Oswestry Disability Index (ODI), Roland Morris Disability Questionnaire for

Sciatica (RMDQ), self perceived recovery according to the patient (Likert), VAS

leg pain, quality of life (EQ-5D), re-surgery, complications, and fusion

(evaluated on CT).

Study description

Background summary

Spondylolisthesis is a relatively frequent pathology of the spine, in which patients usually present with radicular leg pain, with or without low back pain. Whenever the complaints are persistent and invalidating, patients will be offered surgery. The most common procedure is the conventional instrumented surgery with bilateral muscle dissection, decompression of the nerve roots, and correction of the spondylolsthesis with pedicle screw fixation and intercorporal fusion with cages. The last decade, minimally invasive surgery is popularized whereby percutaneous pedicle screws are placed and the nerve roots are decompressed through a small median incision. The rationale of minimally invasive surgery is less muscle damage, reduced postoperative low back pain, and faster recovery. However, until now no randomized controlled trial has been performed on patients with spondylolisthesis, in which minimally invasive

fusion is compared with conventional open surgery.

Study objective

To document whether patients treated with minimally invasive surgery experience less back pain at 2 and 6 weeks after surgery, compared to patients treated with conventional open instrumented surgery.

Study design

Prospective randomized controlled trial.

Intervention

Minimally invasive spondylodesis versus conventional open spondylodesis.

Study burden and risks

Patients will frequently fill out questionnaires, have multiple outpatient visits with radiographic examinations, but there are no disadvantages, risks, or side-effects related to participation in the trial.

Contacts

Public
Selecteer

Lijnbaan 32
Den Haag 2512 VA
NL
Scientific
Selecteer

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age between 18 and 75 years.
* Neurogenic claudication or radicular leg pain with or without low back pain.
* Degenerative or spondylolytic spondylolisthesis grade I or II with spinal stenosis.
* Persistent complaints for at least 3 months, regardless conservative treatments.
* Be able to understand the Dutch language and comprehend the questionnaires and patient information.
* Written informed consent given.

Exclusion criteria

* Previous spine fusion surgery at the same level.
* More than 1 symptomatic level that need fusion.
* Osteoporosis.
* Active infection or prior infection at the surgical site.
* Active cancer.
* Contraindication for surgery.
* Severe mental or psychiatric disorder.
* Alcoholism.
* Morbid obesity (BMI > 40).
* Pregnancy.
* Inadequate knowledge of Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2015
Enrollment:	184
Type:	Actual

Ethics review

Approved WMO

Date:	15-08-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	30-10-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	02-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-06-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT
CCMO	NL49044.098.14