Minimally invasive lumbar fusion versus conventional open lumbar fusion in the treatment of patients with spondylolisthesis.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28885

Source
Nationaal Trial Register

Brief title
MISOS

Health condition

minimally invasive surgery, spondylolisthesis, lumbar fusion, spine surgery.

minimaal invasieve chirurgie, spondylolisthesis, lumbale fusie, wervelkolom chirurgie

Sponsors and support

Primary sponsor: Medical Center Haaglanden
Source(s) of monetary or material Support: Biomet

Intervention

Outcome measures

Primary outcome

Score on the Visual Analoge Scale (VAS) for low back pain (ranging from 0 - 100 mm) in the first 6 weeks after surgery.

Secondary outcome

Oswestry Disability Index (ODI), 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

Patients treated with MIS will document lower back pain scores on VAS at the short-term follow-up (first 6 weeks after surgery) as compared to open surgery.

Study design

baseline, 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 24 months postoperative.

Intervention

Minimally invasive lumbar pedicle screw fixation with interbody fusion, versus open conventional pedicle screw fixation with interbody fusion.

Contacts

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Eligibility criteria

Inclusion criteria

• Age between 18 and 75 years.

• Neurogenic claudication or radicular leg pain with or without low back pain.

• Degenerative or spondylolytic spondylolisthesis 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 surgery at the same level.

• Inflammatory arthritis, osteoporosis or other metabolic bone disease that would influence fusion.

• Contraindication for surgery.

• Severe mental or psychiatric disorder.

• Inadequate knowledge of Dutch language.

• Planned (e)migration abroad in the year after inclusion.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	184
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4335
NTR-old	NTR4532
Other	METC : 14-046

Study results

Summary results
NA