Cost-effectiveness of minimal invasive spinal fusion compared to open fusion for patients with spinal stenosis with neurogenic claudication or radicular leg pain.

Published: 02-06-2014
Last updated: 23-04-2024

What is the cost-effectiveness of minimal invasive posterior lumbar interbody fusion in spinal stenosis patients, compared to the standard open fusion?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41403

Source
ToetsingOnline

Brief title
Cost-effectiveness of Minimal Invasive fusion (DOMINO)

Condition

- Joint disorders
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
low back pain, Neurogenic claudication, radicular leg pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW Doelmatigheidsonderzoek,ZonMW requires co-funding. Unrestricted co-financing was obtained by Medtronic Inc.

Intervention

Keyword: Minimal invasive surgery, Neurogenic claudication, Spinal fusion, Spinal stenosis

Outcome measures

Primary outcome

Primary outcome parameter is the time spent in recovered state during the first

year on the Oswestry Disability Index (ODI).

Secondary outcome

Secondary outcome parameters are Quality of life (EuroQoL, transformed QoL VAS,

SF36), cost, VAS leg and VAS back pain, ZCQ, Likert perceived recovery, Likert

satisfaction, complications, perioperative morbidity, fusion.

Study description

Background summary

Minimal invasive surgery is expected to increase the length of recovery after lumbar spine spondylodesis and thereby lowering the cost from societal perspective (faster return to work, less medical consumption, shorter hospital stay, fewer infections).

Study objective

What is the cost-effectiveness of minimal invasive posterior lumbar interbody fusion in spinal stenosis patients, compared to the standard open fusion?

Study design

Multicenter, randomized controlled trial.

Intervention

Intervention: One level, minimal invasive surgery for decompression and interbody fusion. Minimal invasive access for decompression is accomplished by a muscle splitting approach using tubular retractors. Interbody fusion is accomplished through the same muscle corridors. Screw and rod fixation will be added through 4 additional small incisions.
Control intervention: Standard open decompression and interbody fusion with relatively large midline incision and muscle detachment from the midline bone. Screw and rod fixation through the same open access.

Study burden and risks

This study is judged as having negligible (*verwaarloosbaar*) risks due to participation. There is a concern for nerve root damage from inserting the screws, due to the reduced view of the operative field. But an increased risk has not been observed in current effectiveness trials. The burden for the patient of participation are extra site visits, one blood sample, and the completion of questionnaires and diaries.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Neurogenic claudication or radicular leg pain.
- Complaints are due to MRI confirmed existence of lytic or degenerative spondylolisthesis of maximal 50% or Meyerding Grade II, or spinal stenosis accompanied by severe facet degeneration (grade 2 or 3 according to Weishaupt (Skeletal Radiol 1999; 28 (4):215-9), at one or two levels
- Single or double level fusion indicated.
- Insufficient response to conservative therapy (physical therapy, analgesic medications, or trans-foraminal corticosteroid injections) for at least 6 months.
- Age is between and including 18-70 years.
- Be able to understand the Dutch language and comprehend the questionnaires and patient information.
- Patients signed informed consent.

Exclusion criteria

- Iatrogenic Spondylolisthesis or more than 50% or more than Meyerding Grade II.
- Inflammatory arthritis, Osteoporosis or other metabolic bone disease to a degree that it would influence fusion.
- Contraindication for surgery.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2015
Enrollment:	340
Type:	Actual

Medical products/devices used

Generic name:	Surgical instruments for minimal invasive surgery (example: CD Horizon Sextant/Solera; Serengeti)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-06-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-07-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	03-02-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	04-05-2015
Application type:	Amendment

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	04-06-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-07-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	14-09-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL46777.058.13