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

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Minimal invasive fusion results in a longer time spent in satisfactory symptom state (based on the ODI being below 20) than open fusion of the lumbar spine in patients with one- or two-level spinal stenosis and instability, associated with...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23242

Bron
NTR

Verkorte titel
DOMINO

Aandoening

Included are patients with neurogenic claudication or radicular leg pain due to spinal stenosis which do not respond to conservative therapy for at least 6 months.

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: ZonMW, Medtronic Inc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter is speed of recovery on Oswestry Disability Index (ODI).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Minimal invasive surgery is expected to increase the speed 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).

Objective: The objective of this study is to evaluated the cost-effectiveness of minimal invasive posterior lumbar interbody fusion in spinal stenosis patients, compared to open fusion.

Study design: Multicentre, randomized controlled trial.

Study population: Patients with one- or two-level lumbar spinal stenosis and associated spinal instability with neurogenic claudication or radicular leg pain, unresponsive to conservative treatment, where the spine is likely to destabilize with decompression only.

Sample Size: 340 patients, 170 patients per group, is based on a faster recovery of one month.
Intervention: One- or two-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 insertion and rod fixation will be added through 6 additional small incisions under fluoroscopic guidance or with CT-based computer navigation.

Control intervention: 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.

Main study parameters/endpoints: Primary outcome parameter is the time spent in recovered state during the first year on the Oswestry Disability Index (ODI). Secondary outcome parameters are Quality of life (EuroQoL, transformed QoL VAS, SF36), cost, VAS leg and VAS back pain, Zurich Claudication Questionnaire (ZCQ), Likert perceived recovery, complications, perioperative morbidity, fusion.

Time Schedule: Start-up 3 months; inclusion 30 months; assessments 12 months; analysis and report 3 months. Total 48 months. Assessments will be performed preoperative, at 8 weeks, and 3, 6, and 12 months, with additional assessment of the primary outcome (ODI) at 4 weeks and 4 and 5 months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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, two blood samples, and the completion of questionnaires and diaries.

Doel van het onderzoek

Minimal invasive fusion results in a longer time spent in satisfactory symptom state (based on the ODI being below 20) than open fusion of the lumbar spine in patients with one- or two-level spinal stenosis and instability, associated with neurogenic claudication or radicular pain. The study has a superiority design.

Onderzoeksopzet

at baseline and at 4 and 8 weeks, and 3, 4, 5, 6, 9, and 12 months after randomisation.

Onderzoeksproduct en/of interventie

Intervention:

The intervention arm will be minimal invasive surgery with decompression through a small incision and a computer assisted fusion with an interbody fusion device and posterior instrumentation requiring 6 small skin incisions (4 for the screws and 2 for the connectors) which theoretically gives less damage to the muscles than the conventional muscle detachment and retraction. The surgery can thus be performed with less muscle damage.

Control:

Fusion of lumbar vertebrae by means of posterior screw and rod instrumentation and interbody fusion. In the regular procedure a midline skin incision is made after which the long back muscles are detached from the midline bone and lateralized. All steps of the open procedure are performed through the same incision. In order to get a good overview over the entry point of the screws for the instrumented fusion, the muscles have to be retracted substantially and the muscle has to be detached over a long trajectory. This causes damage to the skin over a long trajectory and damage to the muscles, the latter needing a long rehabilitation period.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A subject must meet all of the following 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, at one or two levels.

- Spine is expected to destabilize after simple lumbar decompressive surgery.

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded:

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-06-2014
Aantal proefpersonen:	340
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-07-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4558
NTR-old	NTR4701
Ander register	: ZonMW Dossiernummer: 80-83700-98-42018

Resultaten