A randomised controlled trial, comparing Surgical Decompression with an Interspinous Implant in patients with Intermittent Neurogenic Claudication caused by Lumbar Stenosis.

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Primary objective is to demonstrate that the effectiveness of thesurgical intervention with Coflex is equivalent to surgical decompression without fusion after 1 year after surgery.Secundary objectives are to demonstrate that surgical intervention...

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

Summary

ID

NL-OMON31834

Source
ToetsingOnline

Brief title
The Felix trial

Condition

- Bone disorders (excl congenital and fractures)
- Therapeutic procedures and supportive care NEC

Synonym
Spinal stenosis & pressure on the nerves causing leg pain

Research involving
Human

Sponsors and support

Primary sponsor: Paradigm Spine / InSpine
Source(s) of monetary or material Support: Paradigm Spine / InSpine

Intervention

Keyword: Lumbar, Spine, Stenosis

Outcome measures

Primary outcome

Symptoms and patient satisfaction will be measured with the Zurich Claudication

Questionnaire.

Secondary outcome

The cost effectiveness as measured by the EuroQol questionnaire and costs

obtained from the patient's diary.

Study description

Background summary

Intermittent neurogenic claudication is a disorder resulting from lumbar vertebral stenosis or a narrowing of the lumbar vertebral canal.
In first instance lumbar vertebral stenosis is treated by non-invasive methods, such as medication and physiotherapy. If symptoms continue to progress or become more painful, surgery to widen the spinal canal can be considered (surgical decompression).
This operation may require an admission period up to 4 days followed by an 8-week recovery period.
In recent years a safe and effective treatment has been developed as an alternative for surgical decompression. An implant will be inserted between the spinal crests which will lead to distraction. The spinal canal and the neural foramina will enlarge and symptoms will decrease. This intervention may require a shorter recovery period.
Previous studies compared the treatment with the Coflex with the non-invasive treatment resulting in significant better results for the Coflex compared to non-invasive treatment.
This study will compare the results obtained with surgical decompression to

results obtained with the Coflex.

Study objective

Primary objective is to demonstrate that the effectiveness of thesurgical intervention with Coflex is equivalent to surgical decompression without fusion after 1 year after surgery.
Secundary objectives are to demonstrate that surgical intervention with the Coflex is more cost effective than surgical decompression and to demonstrate that surgical intervention with the Coflex is more effective on short-term (8 weeks to 6 months).

Study design

A prospective, randomised, blinded study comparison of two treatments.

Intervention

Surgical intervention with the Coflex device.

Study burden and risks

Patient will be asked to visit the hospital pre-operatively and at 8 weeks, 6, 12, 24, and 60 months postoperatively for a follow-up visit. During this visit a neurological examination will be performed and the patient will be requested to complete several questionnaires.
The risks for the patient are the risks associated with surgery under general anaesthesia. When the patient will receive surgical decompression the patient will be subject to similar risks.
Specific risks of treatment with the Coflex are: migration or dislodgement of the implant, no correct positioning of the implant, fracture of the spinous process, lack of efficiviness which may lead to reoperation and removal of the implant.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

signed informed consent - is 45 - 80 years old at time of surgery - has intermittent neurogenic claudicatio - has received at least three months of conservative care therapy - has a regular indication for surgical intervention of INC - has a narrowed lumbar spinal canal, nerve root canal or intervertebral foramen at one or two levels confirmed by MRI - is physically and mentally willing and able to comply with the post-operative evaluations.

Exclusion criteria

- has cauda equina syndrome
- has Paget's disease, severe osteoporosis or metastasis to the vertebrae
- has significant scoliosis
- has a BMI > 40 kg/m2
- has had any surgery of the lumbar spine
- has degenerative spondylolisthesis > grade 1 (on a scale 1 to 4)
- has significant instability of the lumbar spine
- has severe comorbid conditions
- has a fused segment at the indicated level

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2009
Enrollment:	386
Type:	Actual

Medical products/devices used

Generic name:	Coflex
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-04-2008
Application type:	First submission
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	NL21535.058.08