The FELIX trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22839

Source
NTR

Brief title
N/A

Health condition

Lumbar
Spine
Stenosis

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Inspine

Intervention

Outcome measures

Primary outcome

The effectiveness will be measured with the ZCQ score.

Secondary outcome

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

The null hypothesis of this research is that the ZCQ outcome of PDI surgery is similar to the ZCQ outcome os surgical decompression at 1 year after surgery.

Study design

Follow up of all patients will be performed at 8, 26, 52, 104 and 260 weeks after surgery.

Questionnaires will be send by mail.

Intervention

Group A: surgical decompression.

Group B: interspinousis implant.

Contacts

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Eligibility criteria

Inclusion criteria

Patient will be eligible for inclusion in the investigation if he/she

1. Signed informed consent

2. Is 45 - 80 years old at time of surgery

3. Has intermittent neurogenic claudicatio - has received at least three months of conservative care therapy

4. Has a regular indication for surgical intervention of INC

5. Has a narrowed lumbar spinal canal, nerve root canal or intervertebral foramen at one or two levels confirmed by MRI

6. Is physically and mentally willing and able to comply with the post-operative evaluations.

Exclusion criteria

Patient will be excluded from participation in the investigation if he/she

1. Has cauda equina syndrome

2. Has Paget's disease, severe osteoporosis or metastasis to the vertebrae

3. Has significant scoliosis

4. Has a BMI > 40 kg/m2

5. Has had any surgery of the lumbar spine

6. Has degenerative spondylolisthesis > grade 1 (on a scale 1 to 4)

7. Has significant instability of the lumbar spine

8. Has severe comorbid conditions

9. 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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2008
Enrollment:	386
Type:	Actual

Ethics review

Positive opinion

Date:	24-04-2008
Application type:	First submission

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	NL1261
NTR-old	NTR1307
Other	: P08.009
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A