The FELIX trial

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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.

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

Samenvatting

ID

NL-OMON22839

Bron
NTR

Verkorte titel
N/A

Aandoening

Lumbar
Spine
Stenosis

Ondersteuning

Primaire sponsor: Leids Universitair Medisch Centrum
Overige ondersteuning: Inspine

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The effectiveness will be measured with the ZCQ score.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Questionnaires will be send by mail.

Onderzoeksproduct en/of interventie

Group A: surgical decompression.

Group B: interspinousis implant.

Contactpersonen

Publiek

LUMC, afdeling neurochirurgie

SIPS-group Leiden-The Hague
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+31 (0)71 5262144

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	386
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-04-2008
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	NL1261
NTR-old	NTR1307
Ander register	: P08.009
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A