

(Cost) Effectiveness of Surgery versus Prolonged Conservative Treatment in Patients with Intermittent Neurogenic Claudication caused by Lumbar Stenosis.

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Possibly a 6 months prolonged conservative treatment approach with a standardized exercise protocol, education/counseling by the general practitioner, prescription of analgesics and eventually delayed surgery in a smaller population of patients with...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27394

Bron

Nationaal Trial Register

Verkorte titel

ESPRIT Trial

Aandoening

Lumbar stenosis
Neurogenic claudication
Surgical treatment
Nonoperative treatment

Lumbale kanaalstenose
Neurogene claudicatio
Chirurgische behandeling
Non-operatieve behandeling

Ondersteuning

Primaire sponsor: Leids Universitair Medisch Centrum

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Zurich Claudication Questionnaire;

2. Shuttle walking test.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Possibly a 6 months prolonged conservative treatment approach with a standardized exercise protocol, education/counseling by the general practitioner, prescription of analgesics and eventually delayed surgery in a smaller population of patients with persisting complaints is a more (cost)effective approach.

Onderzoeksopzet

Written questionnaires at initial visit, during randomization and at 4, 12, 26, 38, 52, 104, 156, 208, 260 weeks after randomization.

Outpatient clinic physical examination at randomization and 12, 26, 52, 104, 260 weeks after randomization.

Onderzoeksproduct en/of interventie

A 6 months prolonged conservative treatment approach with a standardized exercise protocol, education/counseling by the general practitioner, prescription of analgesics and eventually delayed surgery in a smaller population of patients with persisting complaints.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. At least 50 years old;
2. At least 3 months intermittent neurogenic claudication, as noted by leg/buttock/groin pain with or without back pain or fatigue in the legs provoked by walking. Leg/buttock/groin pain or fatigue needs to be strongly relieved when flexed such as when sitting in a chair;
3. Has a narrowed lumbar spinal canal, nerve root canal or intervertebral foramen at one or more levels confirmed by MRI;
4. Has a regular indication for surgical intervention of INC;
5. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Has a cauda equina syndrome defined as neural compression causing neurogenic bowel

- (rectal incontinence) or bladder dysfunction (bladder retention or incontinence);
2. Has Paget's disease, severe osteoporosis or metastasis to the vertebrae;
 3. Has significant scoliosis (Cobb angle > 25 degrees);
 4. Has a Body Mass Index > 40 kg/m²;
 5. Has previously had a laminectomy at the same level, has degenerative or lytic spondylolisthesis grade >1 (on a scale 1 to 4) at the affected level or has significant instability of the lumbar spine;
 6. Has severe comorbid conditions that will increase the risk to the patient or interfere with the evaluability of this study (e.g. severe ischemic heart disease, musculoskeletal or neurological conditions impairing walking ability, cognitive impairment (MMSE <25 points);
 7. Unable to read or write Dutch.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2010
Aantal proefpersonen:	280
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36278

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2099
NTR-old	NTR2216
CCMO	NL31589.058.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36278

Resultaten

Samenvatting resultaten

N/A