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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27394

Source
Nationaal Trial Register

Brief title
ESPRIT Trial

Health condition

Lumbar stenosis
Neurogenic claudication
Surgical treatment
Nonoperative treatment

Lumbale kanaalstenose
Neurogene claudicatio
Chirurgische behandeling
Non-operatieve behandeling

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Zurich Claudication Questionnaire;

2. Shuttle walking test.

Secondary outcome

1. Demographic data;

2. Neurological/clinical investigations;

3. Modified Roland Disabilty Questionnaire;

4. Visual analogue scale (VAS) for Pain in back and leg;

5. Perceived Recovery;

6. SF-3630;

7. Societal costs and utilities (EuroQol-5D, visual analogue scale);

8. Complications;

9. Re-operation incidence;

10. Operative data;

11. Imaging findings;

12. Patient’s, neurologist’s, neurosurgeon’s, GP’s preference at baseline;

13. Timed-up and go test;

14. Short physical performance battery (SPPB);

15. MicroFET (Force Evaluating and Testing);

16. Grip strength;

17. Accelerometry.

Study description

Background summary

N/A

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Albinusdreef 2
G.M. Overdevest
Leiden 2333 ZA
The Netherlands
+31 (0)71 5262144
Scientific
Albinusdreef 2
G.M. Overdevest
Leiden 2333 ZA
The Netherlands
+31 (0)71 5262144

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	280
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 36278
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2099
NTR-old	NTR2216

Register	ID
CCMO	NL31589.058.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36278

Study results

Summary results
N/A