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

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Intermittent neurogenic claudication due to lumbar stenosis is frequently diagnosed among older persons. Due to an aging population it is to be expected the incidence of lumbar stenosis will increase over time. Patients are operated on because of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON36278

Source
ToetsingOnline

Brief title
The Verbiest Trial

Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
intermittent neurogenic claudication, lumbar stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lumbar stenosis, Neurogenic claudication, Nonoperative treatment, Surgical treatment

Outcome measures

Primary outcome

- Zurich Claudication Questionnaire

- Shuttle walking test

Secondary outcome

- Demographic data

- Neurological/clinical investigations

- Modified Roland Disabilty Questionnaire

- Visual analogue scale (VAS) for Pain in back and leg

- Perceived Recovery

- SF-3630

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

- Complications

- Re-operation incidence

- Operative data

- Imaging findings

- Patient*s, neurologist*s, neurosurgeon*s, GP*s preference at baseline

- Timed-up and go test

- Short physical performance battery (SPPB)

- MicroFET (Force Evaluating and Testing)

- Grip strength

- Accelerometry

Study description

Background summary

Although degenerative lumbar stenosis is frequently diagnosed and various surgical and nonsurgical interventions are widely accepted in clinical practice, there is limited evidence to support many of them, especially in terms of their relative benefit and risk compared with other options. The most common treatment reported in literature is decompressive surgery. In a meta-analysis by Turner et al. successful results are reported 26 to 100% of the subjects with a mean follow-up of nearly 4 years. However various studies observing the natural course of neurogenic claudication also report improvement of symptoms and conclude that expectant observation could be an alternative to surgical treatment. There is no evidence-based data to justify the timing of surgery, which shows a wide variation. Also unknown is whether surgery for lumbar stenosis is cost-effective, compared to prolonged conservative care. Due to a lack of scientific data, confirming a favorable natural course of intermittent neurogenic claudication most Dutch physicians prefer to refer for surgical decompression and instead of prescribing non-invasive methods, such as anti-inflammatory medications and physical therapy. The wide variation in the timing of referral for stenosis surgery depends on factors such as the severity of the symptoms, the inability of patients to cope with the pain during their daily activities or social intercourse and patient and doctor preferences.

Evidence from nonsurgical treatment of neurogenic claudication suggests efficacy for a variety of interventions. At a minimum, patients should receive active physical therapy, education/counseling with home exercise instruction, and a nonsteroidal anti-inflammatory drugs (if tolerated). For patients with inadequate response to nonsurgical interventions and time, surgery is appropriate to consider, but not proven effective. Authors of available studies suggest that surgical treatment provides better short-term outcomes than nonsurgical treatment. As long-term outcomes of non-surgical therapy might be similar to surgery, it is worthwhile to know if early decompressive surgery is really necessary to improve the quality of the aging years. 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 objective

Intermittent neurogenic claudication due to lumbar stenosis is frequently diagnosed among older persons. Due to an aging population it is to be expected the incidence of lumbar stenosis will increase over time. Patients are operated on because of intolerable pain and/or severe decreased daily activities, with the aim of pain relief and conservation or restoration of normal day-to-day activities. The duration of persistent back/leg pain before elective surgery is offered is not a case of evidence-based medicine but is a reflection of normal practice. Although there is consensus that surgery is only offered in the case of persistent pain, the timing of this treatment seems to depend on local production capacity and patient and doctor preferences rather than evidence-based practice. The main goal of this comparative study is to investigate whether a period of at least 3 months of persistent intermittent neurogenic claudication is justified as a solid indication for surgery and superior to a prolonged conservative treatment policy for this condition.

The defined research questions of the proposed study are:

1. Is a policy of conventional surgical intervention more (cost) effective than prolonged conservative care in patients with at least 3 months intermittent neurogenic claudication due to lumbar spinal stenosis?

2. Is it possible to define subgroups of patients who will benefit substantially from one of the two proposed treatment strategies?

Study design

To answer the main research question a prospective, multi-centre comparative randomized clinical trial with parallel group design will be conducted. The follow-up will last 5 years. The multi-centre design is necessary to include the required amount of patients and obtain generalizable results.

All patients presenting to the neurologist of the participating hospitals with complaints of intermittent neurogenic claudication for at least 3 months are eligible for inclusion. The hospitals participating in this study are:

- LUMC Leiden
- MC Haaglanden The Hague and Leidschendam
- Haga Ziekenhuis The Hague
- Bronovo Ziekenhuis The Hague
- Reinier de Graaf Gasthuis Delft
- Vlietland Ziekenhuis Schiedam
- Groene Hart Ziekenhuis Gouda

- Rijnlands Ziekenhuis Leiderdorp
- Diaconessenhuis Leiden
- Lange Land Ziekenhuis Zoetermeer
- Spaarne Ziekenhuis Hoofddorp

The LUMC will function as coordinating hospital for the proposed trial. All participating hospitals take own responsibility for the treatment of subjects. The randomization and collection of study data will be carried out by the research nurse at the outpatient clinics of the participating hospitals.

General practitioners and physical therapists will be informed about the study and asked for their cooperation. They will be directly involved in the study. General practitioners and physical therapists will provide primary care for subjects allocated to prolonged conservative care. Second, general practitioners will be asked to refer patients within 3 months of onset of intermittent neurogenic claudication to the outpatient clinics for evaluation by the neurologist. Patients will be randomized if the diagnosis lumbar stenosis is confirmed by imaging findings. Participants will be allocated to either prolonged conservative care or direct surgery. The general practitioner will provide adequate pain medication and advise the patients to stay active and if possible return to work and/or their leisure activities. Further, patients are prescribed physical therapy that consists of active exercises to guide the patient in upgrading his or her activities according to the agreed time schedule. Patients allocated to the direct surgery group will be operated within 4 weeks after randomization. Early surgery will be compared to a policy of prolonged conservative care.

Demographic and clinical data will be collected at baseline and during consecutive follow-up visits to the outpatient clinics. Further, patients will complete questionnaires and a diary during the follow-up period. Information on pain intensity, physical examination findings, imaging findings, illness related disability, societal costs and utilities and quality of life will be collected. For the cost-effectiveness analysis a societal perspective will be taken, including health care costs and costs due to disability.

Intervention

A prolonged conservative treatment policy will be conducted by the general practitioner (GP) and physical therapist. The GP will check the efficacy of the prescribed pain medication and may adjust the dose or sort of analgesics. Patients are advised to stay active and if possible return to work and/or their leisure activities. They will receive information about the nature of their symtoms/pain. The GP prescribes physical therapy which will consist of active exercises to guide the patient in upgrading his or her activities according to the agreed time schedule. Furthermore, the research nurse will offer counseling by telephone throughout the study period. The protocol for the individual exercise therapy supervised by a physical therapist will include education,

stretching, strengthening and conditioning exercises. Education in proper posture, body mechanics for daily activities, and if necessary, the use of orthopedic aids is essential to maintain the gains made through the physical therapy sessions. The exercise therapy will be discontinued if, according to the physical therapist, treatment goals have been achieved. The guide will be time, not the intensity of the pain. If, six months after randomization, the patient has still not improved or suffers from neurogenic complaints, surgical treatment will be discussed with the patient.

Study burden and risks

Participation in this study imposes no additional risk to patients. Symptoms of lumbar stenosis rarely progress to an acute medical condition (e.g. cauda syndrome or marked or progressive paresis), requiring immediate surgery. Throughout the study period the research nurse and general practitioner will offer counseling and evaluate possible negative health effects of treatment allocation. In case of adverse events related to treatment allocation, the neurosurgeon will be informed. Participants allocated to the prolonged conservative care group will be scheduled for secondary surgery if necessary.

Disadvantages of participating in this study are that subjects are required additional visits to the outpatient clinic for follow-up examinations, intake and randomization. Participants are requested to visit the outpatient clinic 7 times during a 5 year period. Regardles of pariticapating in this study, care as usual also requires patients to make at least 2 visits to the outpatient clinic.

Further, intermittent neurogenic claudication may persist or worsen with prolonged conservative care, necessating secondary surgery. On the contrary, surgery is made redundant in case of symptom relief among participants allocated to prolonged conservative care.

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

-at least 50 years old
-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
-has a narrowed lumbar spinal canal, nerve root canal or intervertebral foramen at one or more levels confirmed by MRI
-has a regular indication for surgical intervention of INC
-informed consent

Exclusion criteria

-has a cauda equina syndrome defined as neural compression causing neurogenic bowel (rectal incontinence) or bladder dysfunction (bladder retention or incontinence)
-has Paget*s disease, severe osteoporosis or metastasis to the vertebrae
-has significant scoliosis (Cobb angle > 25 degrees)
-has a Body Mass Index > 40 kg/m2
-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
-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)
-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
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2011
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-11-2011
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-03-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	14-03-2012
Application type:	Amendment

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	26-03-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-11-2012
Application type:	Amendment
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

ID: 27394
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL31589.058.10