Effectiveness of Small Size Interarcuair Decompression versus Extended Decompression in patients with intermittent neurogenic claudication (SIZE-study): a multi-centre, double-blinded randomized controlled trial

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Primary Objective: To investigate whether small size interarcuair decompression is more effective than conventional laminectomy in patients with INC caused by LSS. Secondary Objective(s): To investigate whether small size interarcuair decompression...

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

Summary

ID

NL-OMON57263

Source
ToetsingOnline

Brief title
SIZE

Condition

- Spinal cord and nerve root disorders

Synonym
lumbar spinal stenosis, narrowing of spinal canal

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lumbar neurogenic claudication

Outcome measures

Primary outcome

5.1.1 Main study parameter/endpoint

The primary outcome measurement will be the Modified Roland-Morris Disability Questionnaire (MRMDQ). This is a 24-point Dutch questionnaire that is designed to assess the physical disability in patients, due to lower back pain. The participant will complete the questionnaire and the sum of the scores reflects the invalidity in daily life. The score can vary from 0 (no restriction) to 24 (severe limitations).

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Secondary outcome

Numeric Rating Scale for leg and back pain

The pain intensity in both legs (affected and non-affected) and back will be rated on an 11-point scale. A score of 0 represents *no pain*, while a score of 10 represents *the most terrible pain I can imagine*. The outcome is the average pain intensity in the legs and back. During each visit the participants are asked to rate the pain for both legs and one for back pain, if applicable. The patient is not entitled to see the pain score indicated during previous

visit(s).

Physical examination consisting of:

- Neurologic examination

A straight leg raise test will be performed. Furthermore, strength, sensibility and reflexes will be assessed of the lower extremity.

- Timed-up and go test

The TUG test will be performed in a standardized manner On *Go,* the patient gets up and walks as fast as possible (no running) to a marked line on the floor at a distance of 3*m. On the line, they turn around by 180° and return to the chair and sit down as quickly as possible. The time between getting up and sitting down again will be recorded in seconds using a stopwatch. The patients are allowed to wear their regular shoes and use a walking aid, if required. Raw TUG test times will be transformed into T-scores using age- and sex-adjusted norms. The TUG app is validated for disc but not for stenosis yet and will be conducted in this study.

- 6-minute walk test (6MinWT)

The 6 -minute walk test is performed to assess the gait pattern, walking speed and physical endurance of patients. The test will be executed on a ground level, where the walked distance can easily be measured, f.i. in a hall with adequate walking space. The patient will be requested to walk at such a speed

that at the end of the 6 minutes, the patient will have the feeling of maximum output. At the end of the 6 minutes, the distance will be measured. During the walking test, the patient is permitted to use a walking aid and/or an orthosis.

- Timed Chair-Stand-Test (TCST)

The Timed Chair-Stand Test is a simple test to evaluate the muscle strength in elderly patients. While conducting the TCST the patient is asked to stand up from his chair and sit down as quickly as possible, for five times. The patient is not allowed to use his arms during this test. The physician will record the time in seconds.

Oswestry Disability Index 2.1a

The ODI is one of the principal condition-specific outcome measures used in the management of spinal disorders. The current version of the ODI (2.1a) is to be used. The ODI has been extensively tested, showing good psychometric properties, and applicable in a wide variety of settings. There are 10 questions (items), each with 6 possible answers; each answer option receives a score of 0 to 5 points, yielding score range between 0 and 50, which is scaled to a 100% range. The questions are designed in a way to realize how the back or leg pain is affecting the patient's ability to manage in everyday life.

Functional lumbar x-rays

A functional X-ray will be obtained from all patients X-ray will be made from AP and lateral position to assess spondylolisthesis. Degenerative

spondylolisthesis is defined as a vertebral slip of at least 3 mm. This will obtained after six weeks, for level verification and for verification of correct procedure and after two years to look for possible instability of the spine.

Likert scales for recovery and satisfaction with treatment

This will be measured using a seven-point Likert scale.

SF-36

The SF-36 has been applied and validated numerous times for intervention studies involving vertebral column pathology. The questionnaire relates to the analysis of the general functional status of the patient. The questions are divided in 8 domains:

Per domain the scores of the items are added up and transformed into a scale of 0 to 100. A higher score reflects a better health condition.

- Physical functioning
- Physical role limitations
- Emotional role limitations
- Social functioning
- Physical pain
- General mental health
- Vitality
- General health perception

Complication and re-operation incidence

The neurosurgeon and research nurse will collect complications precisely. This will be examined specifically in respect of:

• Infections, divided into superficial wound infections and deep wound infections

• Post-surgical haematoma

• An increase in neurological failure due to surgery

• Blood transfusion

• Unintended durotomy

• Nerve injury

• Cardiovascular complications

• Pulmonary complications

• Wrong level surgery

• Wound infection

In numerous studies regarding vertebral column surgery re-operation is considered as a very poor result of the initial surgery and therefore used as effect measure

EuroQoL-5-dimension

The EuroQol (EQ-5D) will be used for the cost utility analysis at the end of the study. As indicated by the name, the tool measures five dimensions:

• Mobility

• Self-care

• Pain/discomfort

• Daily activities

• Anxiety

Each dimension consists of one item, in which three levels are distinguished (no problems, some problems, many problems)

This tool provides the possibility to link the multidimensional description of quality of life to a valuation (or utility). This utility may be linked to the duration of the health situation in question. Together with the remaining life expectation, they form QALY*s. The QALY is a measure for the number of years that someone still may expect, corrected for their quality.

By measuring the utilities, a special type of cost effectiveness analysis is created in which the measured measure is expressed in cost per QALY*s of one treatment compared to the other, less effective treatment.

Together with the VAS, the EuroQol is an important result measure which will be collected by the research nurse during each visit to the outpatient clinic on the basis of the interview. The EuroQol is an effect measure that uses the utilities of the general population and can easily be filled in at home. This as opposed to the Time Trade Off and the SG which will neither be used in this research, having the disadvantage of being complicated for most of the patients and time-consuming for the research nurse.

Cost-diaries

The patient will be requested to keep a diary for the financial aspects of the consequences of INC and corresponding treatment. The patient will be requested

to record the following items:

• Visits to GP

• Visits to physiotherapist

• Visits to specialist

• Alternative medicines and devices (e.g. rollator, etc.)

• Number of days of hospitalization

• Pain medication; dosage and frequency

• Illness-related days of absence at work, if any

• Cost of loss production and substitute manpower, if any

• Additional travelling expenses on account of INC

• Help in house holding

Study description

Background summary

Intermittent neurogenic claudication (INC) caused by a lumbar spinal canal stenosis (LSS) is the most frequent reason for spinal surgery in the elderly. Multiple, less invasive surgical techniques are applied without sufficient evidence for benefits for patients or society.

The classic symptoms of INC are leg pain, which can be exacerbated with prolonged walking and standing and/or lumbar extension, and is associated with back pain. Severe stenosis is common in the elderly spine with 30.4% of the population having severe stenosis. However, only 17.5% have complaints of INC.

Conservative treatment, such as physical therapy or pain medication, may give some relief of symptoms. However, surgical treatment is considered to be the gold standard for patients with INC caused by LSS. The first technique ever described to widen the lumbar spinal canal is the wide bony decompression (laminectomy), which is still a widely used technique. However, since INC is often accompanied by back pain, and this to post-operative back pain, it is hypothesized that a wide decompression is a ground for potential instability. Hence, less invasive techniques, such as interarcuair decompression, were

developed and implemented.

Recent studies claim that a limited bony decompression is the new *golden standard* therapy for patients with INC. Limited bony decompression is believed to give less muscle damage and thus a faster postoperative recovery. Furthermore, wide bony decompression (such as a laminectomy) is believed to result in lumbar instability and iatrogenic scoliosis. Performing a procedure with potential more complications in a - generally - elderly population could at least be described as doubtful. The assumption is often made that after a wide decompression recurrence of the complaints must be scarce. However, a (cost-) effectiveness study, which evaluates the effectiveness of small bony decompression compared to a *classical* extensive bony decompression, has not been performed yet. The opinions on this matter are diverse. A laminectomy involves the removal of more bone and structures at the back of the spine which may result in longer hospitalization and loss of productivity, but it could also lead to spinal instability on the long term. However, the risk of an insufficient decompression may be higher, potentially leading to more reoperations.

By the means of this double-blinded, multi-center randomized controlled trial we will determine the (cost-) effectiveness of a limited bony decompression compared to a wide bony decompression in patients with INC.

Study objective

Primary Objective: To investigate whether small size interarcuair decompression is more effective than conventional laminectomy in patients with INC caused by LSS.

Secondary Objective(s): To investigate whether small size interarcuair decompression is more cost-effective than conventional laminectomy in patients with INC caused by LSS.

Study design

The SIZE study is a researcher- and patient-blinded, multi-center randomized controlled trial with superiority design and 1:1 allocation. The follow-up will take place up to a duration of 48 months after surgery to investigate long-term effect as well. A multicentre study is necessary to include the required number of patients. All participating hospitals are individually responsible for the treatment applied.
Demographic and clinical data will be collected during intake and follow-up measurements. Patients will fill in patient-reported outcome measures via an online research system (Gemstracker).

Intervention

All surgeons involved with the Size-study are highly experienced in both interventions. Both techniques are part of the Dutch training program for neurosurgeons.
The intervention that is to be investigated is the small size interarcuair decompression by bilateral approach. A median lumbar incision is made over the spinous process and the paravertebral muscles are dissected subperiosteally and retracted bilaterally. Decompression will be applied via decompression of the ligamentum flavum and partial laminectomy if necessary. The lateral recess will be opened bilaterally and a medial facetectomy will be performed in order to decompress the neuronal structures in the lateral recess. The wound will be closed in layers with or without a suction drain. Patients will be operated with a loupe magnification or microscope depending on the surgeon*s preference.
The usual care is a conventional laminectomy (Thome 2005). A median lumbar incision is made over the spinous process and the paravertebral muscles are dissected subperiosteally and retracted bilaterally. The supra and interspinous ligament with the spinous process of the affected level are removed and both laminae are removed totally at the affected level. The lateral recess will be opened bilaterally and medial facetectomy will be performed in order to decompress neuronal structures in the lateral recess. To clarify, when a single level stenosis is present (e.g. L4-L5) both laminae L4 and L5 will be removed and when a double level stenosis (e.g. L3-L4 and L4-L5) is present three laminae (L3, L4 and L5) will be removed. The wound will be closed in layers with or without a suction drain. Patients will be operated with loupe magnification or microscope depending surgeon*s preference.

Study burden and risks

As the applied treatment will not differ from the usual care, participating patients will neither benefit nor will they be at risk by participating in this study regardless of the treatment they undergo as far as safety of surgical procedures is concerned. Normally, a a patient would undergo a surgery technique depending on the preference of the surgeon. During this study, the technique, that is going to be used, depends on randomization, Other drawbacks for participating include the extra time for completing the questionnaires, visiting the research nurse and the additional risk of radiation due to exposure during the X-rays.

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 12 weeks of complaints of Intermittent Neurogenic Claudication
- Indication for an operation
- Magnetic Resonance Imaging demonstrating Lumbar Spinal Stenosis
- Age above 40 years
- Sufficient knowledge of the Dutch language in order comprehend the questionnaires and patient information.
- Written informed consent given

Exclusion criteria

- History of lumbar surgery
- More than 2 lumbar levels operation or needed discectomy
- Degenerative spondylolisthesis greater than grade I (on a scale of I to IV)
- Scoliosis or disc herniation
- Severe comorbid medical disorder (American Society of Anesthesiologists > 3)
- Serious psychopathologic disorder
- Pregnancy
- Active malignancy
- Plans to move abroad during study period.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2019
Enrollment:	174
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-04-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT03480893
CCMO	NL65926.078.18