A Multicenter Prospective Randomized Controlled Clinical Trial to Evaluate the Effectiveness and Safety of the Aperius* PercLID*System Versus Standalone Decompressive Surgery in Degenerative Lumbar Spinal Stenosis with Neurogenic Intermittent Claudication.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36302

Source
ToetsingOnline

Brief title
NICE - Neurogenic Intermittent Claudication Evaluation study

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
lumbar spinal stenosis - narrowing of the spinal canal

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic Spinal & Biologics Europe

Intervention

Keyword: - Aperius PercLID System, - Degenerative Lumbar Spinal Stenosis (DLSS), - Neurogenic Intermittent Claudication (NIC), - Standalone Decompressive Surgery (SDS)

Outcome measures

Primary outcome

The primary endpoint of the study is the mean percentage change from baseline in Physical Function at 1 year follow-up using the study subject completed Zurich Claudication Questionnaire (ZCQ).

Secondary outcome

- Mean percentage change from baseline in Physical Function, using the study subject completed ZCQ at 14 days, 6 weeks, 6, 24, 36, 48 months

- Mean percentage change from baseline in Symptom Severity, using the study subject completed ZCQ at 14 days, 6 weeks, 6, 12, 24, 36, 48 months

- Percentage of patients being satisfied with the treatment assessed using the study subject completed ZCQ at 14 days, 6 weeks, 6, 12, 24, 36, 48 months

- Mean percentage change from baseline in Leg Pain VAS Scores at 14 days, 6 weeks, 6, 12, 24, 36, 48 months

- Mean percentage change from baseline in Quality of Life using the study subject completed SF-36 v2 questionnaire at 14 days, 6 weeks, 6, 12, 24, 36, 48 months

Note: The SF-36 v2 questionnaire profiles physical and mental health in 8 different dimensions including: Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, Mental Health, each of which will be analyzed separately and combined as physical component summary (PCS) and mental component summary (MCS).

- Changes in the stenosis of the spinal canal assessed by MRI at the follow-up time points
- Changes in the bony structures assessed by CT at the follow-up time points
- Percentage of subjects requiring surgical intervention at the index level in the follow-up period
- Proportion of subjects with complications at the secondary surgical intervention
- Proportion of subjects with SADE*s
- Determining if there is a correlation between sagittal balance or other radiological findings and the clinical outcomes
- Proportion of subjects with improvement of symptoms, symptoms recurrence, decreased therapeutic response, no therapeutic response and treatment failure at 14 days, 6 weeks, 6, 12, 24, 36, 48 months

Study description

Background summary

Degenerative Lumbar Spinal Stenosis (DLSS) is a slowly progressing disease, characterized by narrowing of the spinal canal and/or the neural foramina by degenerative changes in the spine: such as hypertrophy of the facet joints, folded and thickened yellow ligament, formation of osteophytes, and bulging of

the intervertebral disc.
Symptom relief can be obtained by relieving the pressure on the neural structures of the back. This study will compare 2 surgical procedures, (that are also available without participation to the study): standalone decompressive surgery and the Aperius* PercLID* System .

Study objective

The objective of the study is to provide clinical evidence proving that the Aperius* PercLID* System is safe and non-inferior to Standalone Decompressive Surgery (decompressive spinal surgery without additional instrumentation/fixation) with regards to clinical outcomes in patients suffering from DLSS with Neurogenic Intermittent Claudication (NIC), relieved by flexion.

Study design

A Multicenter Prospective Randomized Controlled Clinical Trial to Evaluate the Effectiveness and Safety of the Aperius* PercLID*System Versus Standalone Decompressive Surgery in Degenerative Lumbar Spinal Stenosis with Neurogenic Intermittent Claudication. The anticipated duration of the study includes approximately 24 months for recruitment and 48 months follow-up, for a total of approximately 72 months.

Intervention

Depending on the outcome of the randomization, the study subject will receive either the Aperius* procedure or the Standalone Decompressive Surgery.

Study burden and risks

Risks:

1)There is exposure to radiation from X-rays and CT*s taken to diagnose and follow up the spinal stenosis, the implant after surgery (in the Aperius* PercLID* System arm) or the status of your spine (in the Standalone Decompressive Surgery arm). There is also radiation exposure during both surgeries from fluoroscopy that is needed for precise navigation during both types of surgery. The radiation may be harmful to an unborn child. Thus, a woman who is or could become pregnant, must have a pregnancy test done prior to enrolment into the study. If the test is positive, these tests will be cancelled, and study subjects will not be eligible for enrolment into this study. Also breastfeeding will exclude from participation. MRI involves no radiation exposure.
2)Possible risks related to surgery in general (for both study groups). Every surgical procedure and medication to put study subject asleep has certain

risks. These risks are independent from participation in this study. Potential risks to any surgical procedure include but are not necessarily limited to:
-Thrombosis/emboli
-Hematoma
-Reaction to anesthesia
-Allergic reaction to medication
-Blood loss
-Infection / inflammatory reaction / fever
-Problems with the heart and/or the lungs
-Psychological problems
3)Possible risks related to the Aperius* PercLID* System
-Dislocation or migration of the implant
-Foreign Body reaction -
-Device malfunction
-Allergy to Device materials
-Spinous Process Fracture
-Persistence of pain or worsening of symptoms
-Revision surgery (with or without removal of the device)
-Subsidence of the Aperius* into the spinous processes
-Damage to the facet joints
-Temporary back pain at the implanted level due to the incision and/or stretching of the ligaments and/or change in posture
4)Possible risks related to the Standalone Decompressive Surgery
-Damage to ligaments
-Persistence of pain or worsening of symptoms
-Fractures of the bones of the back
-Damage to nerve roots
-Dural tears (leakage of the fluid around the spinal nerve, due to damage of the protecting tussue)
-Cauda Equina syndrome (includes symptoms of back and leg pain, urinary retention, fecal incontinence, numbness and weakness in the legs and abnormal gait)
-Revision surgery
-Lumbar instability (due to the removal of bony and/or ligamentous tissue in the treated spine segment)
-Paraplegia

Benefits:
If successful, either treatment will partially or completely resolve study patients' symptoms associated with the Lumbar Spinal Stenosis, restore or improve study patients ability to move and walk, decrease or eliminate the back/leg/buttock/groin pain and may improve the quality of life.
Patients do not need to participate in this study to receive these treatments and its benefits, the information from this study can help doctors to understand how to improve the handling and treatment of patients suffering from Degenerative Lumbar Spinal Stenosis. Information collected in this study can support the development of new devices and therapies.

At this point in time we do not know exactly if the treatment with the APERIUS* PercLID* System provides the same results as treatment with Standalone Decompressive Surgery, by means of this trial we would like to find this out. In general we expect to obtain good results for both treatment groups with regards to improvements in back / leg / buttock / groin pain, physical function and quality of life.

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

*Presence of symptomatic DLSS in the L1-L5 region confirmed by MRI at 1 or maximum 2 levels
*Presence of NIC, defined as a feeling of paresthesia and/or discomfort and/or pain and/or weakness in the leg(s) during walking or prolonged standing, with or without back pain,

buttock and/or groin pain which are relieved in flexion
*Leg pain must be more pronounced than back pain. Leg pain VAS score must at least be 2 points higher than back pain VAS score.
*Average disc height *defined as the mathematical mean of the anterior and the posterior disc height measured in the mid-sagittal MRI- at the index level(s) is * 5mm.
*According to the current standard of care patient would be candidate for Standalone Decompressive Surgery (no instrumentation, no stabilization or fusion)
*Patient states availability and willingness to perform all follow-up examinations
*Patient has signed Informed Consent form (ICF)
*Patient is 21 years old or older
*Duration of the patient*s leg symptoms is at least 6 weeks at screening
*Patient has no financial interest in participating in the study (e.g.: workers compensation etc)

Exclusion criteria

*Patient had undergone a previous lumbar surgery at any lumbar level
*Patient has unremitting pain (leg, buttock/groin) in any spinal position
*Patient is candidate for instrumented decompressive surgery (decompression with stabilization/fusion)
*Patient has back pain without leg pain
*Degenerative Spondylolisthesis greater than Grade 1 on the Meyerding grading system
*Spondylolysis (fracture or defect of the isthmus/pars interarticularis)
*Spinous process fracture at any lumbar level
*Ankylosis at the affected level
*Fixed motor deficit
*Symptomatic DLSS at more than 2 levels in the lumbar region
*Spinal stenosis is present at L5-S1 level
*Symptomatic disc herniation causing radiculopathy
*Patient*s anatomical features do not allow appropriate placement of the device
*BMI of patient equal to or higher than 35
*Scoliosis with Cobb angle * 25°
*Kyphosis requiring surgical correction
*Paget*s disease
*Tumor of the spine
*Presence of vascular claudication
*History of one or more osteoporotic spinal fragility fracture(s), determined on full spine X-ray
*Active systemic infection or local infection at the target level(s)
*Major Depression according to the DSM IV criteria
*Dementia and/or inability to give Informed Consent
*Unable to complete the study
*Pregnancy, breastfeeding or planned pregnancy
*Allergy to any of the components of the Aperius device, inserter or the distractors.
*Patients with specific contraindications for MRI: (claustrophobia, cardiac pacemaker, implanted cardiac defibrillator, aneurysm clips, neurostimulator, insulin pump, implanted

drug infusion device, bone growth/fusion stimulator and cochlear -, or otologic implant)

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Aperius PercLID System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-09-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT00905359
CCMO	NL28522.098.10