The PLUS Study: Preventing Lumbar disc surgery

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Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON50214

Source
ToetsingOnline

Brief title
PLUS study

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
sciatica and herniated nucleus pulposus

Research involving
Human

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMW,Rugpoli

Intervention

Keyword: Injection, MDT, Sciatica, Surgery

Outcome measures

Primary outcome

Surgery rate (number of patients undergoing surgery during a 12-month follow-up)

Secondary outcome

Back and leg pain intensity (NPRS), physical functioning (RMDQ-23), self-perceived recovery (GPE), health-related quality of life (EQ-5D-5L) en societal costs.

Study description

Background summary

Lumbar disc surgery rates in the Netherlands are high. It is estimated that 12,000 operations are performed yearly in the Netherlands. The incidence rate of Lumbosacral Radicular Syndrome (LSRS) in general practice is 12 per 1,000 patients per year. The Dutch guideline 'Lumbosacral Radicular Syndrome (LSRS, also known as sciatica)' recommends surgical treatment if the radiating leg pain persists in spite of a period of conservative management.

A significant number of patients undergoing surgery for lumbar disc herniation suffer residual complaints. Surgical and non-surgical management of lumbar hernia are equally successful in the long term. However, withholding surgery to patients whose complaints persist after often a long period of conservative management is challenging. Although preventing surgery has the potential to improve patient outcomes and reduce costs.

Results of our pilot study suggest that the provision of a combination therapy consisting of Mechanical Diagnosis and Treatment (MDT) and Transforaminal epidural steroid injections (TESIs) can lead to a reduction in the number of operations (ie, only 22% of the patients underwent surgery after 1 year of follow-up). However, our pilot study was not an RCT. We hypothesize that the combination therapy will prevent at least 30% of the lumbar herniated disc

surgeries as compared to usual care (i.e. the wait list arm in our RCT).

Study objective

The primary objective of this study is to assess the effectiveness and cost-effectiveness in terms of the number of surgeries prevented of a combination therapy versus usual care.
The secondary objective of this study is to assess the effectiveness and cost-effectiveness in terms of pain (leg and back), functioning, self-perceived recovery and health-related quality of life of a combination therapy versus usual care.

Study design

Randomized controlled trial with economic evaluation (societal & healthcare perspective). Treatment allocation is concealed. We will use one randomization scheme per hospital (unit of randomization is patient).

Intervention

The combination intervention (MDT and TESIs) will be administered as follows; Using MDT principles and based on pain responses, participants are classified as centralizers or non-centralizers. Centralizers get specific MDT exercises and advice. Non-centralizers will be injected with dexamethasone 20 mg and lidocaïne 0.5cc 2% under fluoroscopic guidance with contrast medium. If pain reduction is less that 50%, then a second injection will be administered with patient consent. After the injections, participants will be re-classified using the same MDT principles into 4 subgroups. The subgroups are as follows;1) resolved symptoms; 2) centralizing and significantly less pain, 3) non centralizing and significantly less pain and 4) non-centralizing with high levels of pain. In the first three groups mentioned here, patients will be given advice and treated according to MDT principles with direction-specific exercises and posture correction. Each subgroup will be treated by the MDT therapist (1 to 6 session in on average 4 weeks). Only the patients in the subgroup; non-centralising with high levels of pain will be referred back for surgery.

Patients randomized to the control intervention group will placed on a waiting list and scheduled to receive lumbar disc surgery within 2-4 months, if still required. The aim of surgery is to remove the symptomatic disk herniation by a minimal unilateral transflaval approach with magnification, with the patient under general or spinal anesthesia.

Study burden and risks

The risks associated with participation in this study are equal to the risks

associated with daily practice. In the PLUS study we do not deviate from daily practice. In the Netherlands patients suffering from sciatica can either receive an operation or be treated using conservative methods. Conservative methods include transforaminal steroid injections and physiotherapy/McKenzie treatment, both of which are interventions offered in this study. Therefore there is no risk to participants for taking part in this study.

Patients will be required to complete questionnaires at various moment and this might be regarded as extra burden for patients.. The benefits of this study will outweigh this extra burden. Currently more than 1.2 million per year is associated with direct and indirect costs of sciatica in Netherlands. This project will provide an answer to the question whether combination therapy is cost effective compared to surgery in patients with lumbar hernia. The result will guide evidence-based decision making for patients who (based on current guidelines) undergo lumbar disc surgery. Thereby reducing the burden on patients and society.

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

• Incapacitating lumbosacral radicular syndrome with leg pain, NRS>6, (with or without back pain) that had lasted for a minimum of 6 weeks with or without mild neurological deficit, medical research council (MRC) muscle scale higher than 3
• Magnetic resonance imaging (MRI) which confirms a lumbar HNP that compromises the spinal nerve and can explain the clinical symptoms of the patient
• The patients should according to usual care have an indication for lumbar HNP operation by a neurosurgeon.
• Signed informed consent for participation in the study
• 18 years and above

Exclusion criteria

• Patients suffering from cauda equina syndrome
• Previous spine surgery at the same level during the previous 6 months
• Previous transforminal injections at the same level during the previous 6 months
• Bony stenosis
• Spondylolisthesis
• Pregnancy
• Complicated disc herniation requiring more operations
• Severe coexisting disease e.g. osteoporosis, dementia
• Patient with contra-indications for steroids injections
• Insufficient knowledge of the Dutch language
• Emergency surgery as determined by the neurosurgeon
• Being allergic for OMNIPAQUE 240

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	146
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xylocaine 20mg/ml
Generic name:	lidocaïnehydrochloride 20 mg/ml
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	20-07-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	07-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	25-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	19-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2017-002119-33-NL
CCMO	NL60558.029.17