Preventing lumbar disc surgery

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22180

Source
NTR

Brief title
The PLUS study

Health condition

herniated nucleus pulpos patients

Sponsors and support

Primary sponsor: VU Amsterdam, Faculty FALW, Dept. of Health Sciences, room T557, De Boelelaan 1085, 1081 HV Amsterdam, The Netherlands
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Surgery rate, number of patients undergoing surgery during a 12-month follow-up.

Secondary outcome

- Self-reported leg pain (0-100 numeric pain rating scale (NPRS)), Timepoint: baseline, 4 weeks, 2 months, 4 months, 6 months, 9 months, 12 months.

- Self-reported back pain (0-100 NPRS), Timepoint: baseline, 4 weeks, 2 months, 4 months, 6 months, 9 months, 12 months.

- Functional status (Roland Morris Disability Questionnaires (RMDQ-23)), Timepoint: baseline, 2 months, 4 months, 6 months, 9 months, 12 months.

- Self-perceived recovery (Global Perceived Effect scale), Timepoint: 2 months, 4 months, 6 months, 9 months, 12 months.

- Health-related quality of life (SF-12; EQ-5D-5L), Timepoint: baseline, 2 months, 4 months, 6 months, 9 months, 12 months.

- Societal and healthcare costs, Timepoint: baseline, 2 months, 4 months, 6 months, 9 months, 12 months.

Study description

Background summary

Lumbosacral radicular syndrome is commonly caused by a herniated nucleus pulposus. In the past decade, in the Netherlands, the incidence rate of sciatica has increased from 75 000 to 85000 per year, resulting in around 1.2 billion euros in direct and indirect costs per year. The majority of sciatica patients end up receiving surgery even though conservative treatment was previously found to be equally successful at long term follow-up. Moreover, surgery is associated with high costs and complications. Conservative methods for sciatica include transforaminal epidural steroid injections and physiotherapy/mechanical diagnosis therapy, both of which have been reported to be individually successful treatments. However, as far as we are concerned, our pilot study was the only study that has assessed the effects of a combination therapy, consisting of mechanical diagnosis therapy and transforaminal epidural injections, in reducing surgery rates. Hence, this study aims to determine if such a combination therapy, while being on the waiting list for a lumbar herniated disc surgery, is effective and cost-effective compared to usual care (i.e. no intervention while being on the waiting list) in reducing surgery rates among HNP patients with an indication for a lumbar herniated disc surgery.

Study objective

A combination therapy (MDT and TESIs) is effective and cost-effective compared to usual care among herniated nucleus pulpos patients with an indication for a lumbar herniated disc surgery

Study design

Timepoint: baseline, 4 weeks, 2 months, 4 months, 6 months, 9 months, 12 months.

Intervention

Intervention condition: Mechanical Diagnosis and Treatment (McKenzie treatment) (with Transforaminal Epidural Steroid Injection(s)) while being at the waiting list to receive lumbar disc surgery.

Control condition: Being at the waiting list to receive lumbar disc surgery.

Contacts

Public
Postbus 7057
R.W.J.G. Ostelo
Van der Boechorststraat 7
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4448149
Scientific
Postbus 7057
R.W.J.G. Ostelo
Van der Boechorststraat 7
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4448149

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following 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 (i.e. Medical Research Council [MRC]>3).

• MRI which confirms a 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 HNP operation by a neurosurgeon.

• Signed informed consent for participation in the study

• 18 years and above

Exclusion criteria

A potentially eligible subject who meets any of the following criteria will be excluded from participation in this study:

• Patients suffering from cauda equina syndrome

• Previous spine surgery at the same level during the previous 6 months

• Previous transforaminal injections at the same level during the 6 months

• Bony stenosis

• Spondylolisthesis

• Pregnancy

• Complicated disc herniation requiring more than one operation

• 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 Iohexol 240mg/ml (i.e. OMNIPAQUE 240)

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):	01-10-2017
Enrollment:	146
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-09-2017
Application type:	First submission

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
NTR-new	NL6527

Register	ID
NTR-old	NTR6715
Other	CCMO - NL60558.029.17 : ZONmw - 80-84300-98-71005

Study results