Preventing lumbar disc surgery

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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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22180

Bron
Nationaal Trial Register

Verkorte titel
The PLUS study

Aandoening

herniated nucleus pulpos patients

Ondersteuning

Primaire sponsor: VU Amsterdam, Faculty FALW, Dept. of Health Sciences, room T557, De Boelelaan 1085, 1081 HV Amsterdam, The Netherlands
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	146
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-09-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6527
NTR-old	NTR6715
Ander register	CCMO - NL60558.029.17 : ZONmw - 80-84300-98-71005

Resultaten