Cervical radicular pain: A randomised controlled trial comparing percutaneous plasma discectomy and anterior cervical discectomy.

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

Summary

ID

NL-OMON43793

Source
ToetsingOnline

Brief title
Percutaneous plasma discectomy study

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Spinal cord and nerve root disorders

Synonym
cervical radicular pain

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: cervical radicular syndrome, nucleoplasty, nucleotomy, percutaneous plasma discectomy

Outcome measures

Primary outcome

The influence of treatment on the intensity of pain, the global perceived

effect.

Secondary outcome

The functional status and the health-related quality of life and

cost-effectiveness

Study description

Background summary

Several treatments exist for the treatment of the cervical radicular syndrome caused by a contained soft disc hernia. The effects of an open nucleotomy, physiotherapy and cervical collar were studied by Persson (Feldborg Nielsen, Annertz et al. 1997; Persson, Carlsson et al. 1997). They concluded that on the short term pain improved much faster by surgery. On the long term muscle force, sensibility and pain improved as well.
Kuijper (Kuijper, Tans et al. 2009; Kuijper, Tans et al. 2009) investigated the effects of conservative treatment for the cervical radicular syndrome, and concluded that a semi-hard cervical collar and rest for three to six weeks or physiotherapy accompanied by home exercises for six weeks reduced neck and arm pain substantially compared with a wait and see policy in the early phase of cervical radiculopathy.
Cesaroni et al. (Cesaroni and Nardi 2009) studied percutaneous plasma discectomy and found significantly better clinical outcomes than a conservative care regimen.
Up till now no studies have been performed that compare the results of

percutaneous plasma discectomy with open nucleotomy.
Since the complications of open nucleotomy include a small risk on local inflammation, local pain, and a longer period of convalescence, it would be considered an important improvement, if the same advantages of open nucleotomy could be achieved with percutaneous plasma discectomy being much less invasive.

Study objective

The aim of this study is to compare the effects of anterior cervical discectomy versus percutaneous plasma discectomy on pain, on global perceived effect, functional status and health-related quality of life in a group of patients with cervical radicular pain caused by a contained soft disc herniation.

Study design

A multicenter randomised controlled parallel-group study

Intervention

Two different treatment methods will be compared in patients with a contained disc hernia: anterior cervical discectomy and percutaneous plasma discectomy.

Study burden and risks

All two treatments are standard procedures in the participating treatment centers, so the patients will undergo no additional treatment, and will not be exposed to any additional risks by participating in the trial. The burden associated with participation is that they will have to fill out a number of online questionnaires, and undergo the following tests: Muscle strength; Upper Limb Activity Monitor, Quantative Sensory Testing, and DNIC, at two regular clinic visits (T0 and T2), and that they will have to make one extra visit to the clinic to perform the same tests (T3).

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

Radicular pain of the lower cervical spine (C4-7) with complaints of radicular pain (VAS (0-100) as a result of a contained soft disc hernia with or without neck pain, without improvement in at least 8 weeks of conservative therapy.

Exclusion criteria

Age below 18 and above 65 years; Pregnancy; Anticoagulant drug therapy and/or disturbed coagulation; Infections/ tumours; Previous spinal surgery in cervical region; Extruded disc fragment; bony spurs; calcified disc; Herniation > 5 mm; Disc: maximal 50% loss of height; Neurodegenerative diseases, including lesions of the spinal cord; Lack of cooperation of the patient; Patients who are not able to complete the questionnaires, according to the referring doctor; Drugs/medication/ alcohol addiction; Serious psychopathology;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2012
Enrollment:	94
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-10-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-12-2016
Application type:	Amendment
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
CCMO	NL32745.078.10