Percutaneous Cervical Nucleoplasty vs. Pulsed Radio Frequency in patients with contained cervical disc herniation; a double-blind randomized clinical trial

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To investigate which technique is the most effective in terms of pain relief on short term in patients with contained cervical disc herniation: PCN or PRF?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON37639

Source
ToetsingOnline

Brief title
Percutaneous Cervical Nucleoplasty vs. Pulsed Radio Frequency

Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
Hernia Nuclei Pulposi and disc herniation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Annaziekenhuis

Source(s) of monetary or material Support: Financiering door vakgroep pijnbestrijding

Intervention

Keyword: Cervical, Herniation, Nucleoplasty, Radiofrequency

Outcome measures

Primary outcome

The main study parameter to measure efficacy of both treatments is pain. Pain is measured using a 100 mm Visual Analogue Scale (VAS-100 mm) and a Verbal Rating Scale using 5 categories (VRS-5).

Secondary outcome

Secondary endpoints will include:

- The Short Form 12-item questionnaire for general health (SF-12);

- The Neck Disability Index (NDI) for neck functioning during ADL;

- The Multidimensional Pain Inventory - Dutch Language Version (MPI-DLV) for assessing a number of dimensions of chronic pain experience, including pain intensity, emotional distress, cognitive and functional adaptation, and social support;

- Changes in limitations in sports and work, including return to work-rate;

- Recording of (serious) adverse events ((S)AEs) to investigate the safety of both treatments, focusing on the number and percentage of (S)AEs. Also the intensity of treatment related adverse events will be reported;

- Patient*s study diary for cost-effectiveness evaluation, including use of (escape) medication and physician visit(s);

- Difference in patient*s drug regime before and after treatment;

- Patient satisfaction with treatment (result) measured dichotomously via a

question and continuously via VAS-100 mm.

Study description

Background summary

Pain management in cervical disc herniation relies initially on conservative care (rest, physiotherapy, and oral medications). Once conservative treatment has failed, different percutaneous minimally invasive (radiological) procedures can be applied to relief pain. Percutaneous Cervical Nucleoplasty (PCN) is the most often applied technique on the cervical level with a low risk of thermal damage. A variety of published studies have demonstrated PCN to be both safe and effective. Pulsed Radio Frequency (PRF) of the dorsal root ganglion is also a popular pain treatment modality for a variety of pain syndromes. The application of PRF is also a safe and useful intervention for cervicular pain. Although these treatment modalities are described in the literature, the available evidence for efficacy is not sufficient to allow definitive conclusions on the optimal therapy to be made.

Study objective

To investigate which technique is the most effective in terms of pain relief on short term in patients with contained cervical disc herniation: PCN or PRF?

Study design

A single-centre double-blind randomized clinical trial.

Intervention

Included patients will be randomized into either of two study groups, receiving cervical nucleoplasty or PRF.

Study burden and risks

Regardless the treatment group to which the patient is allocated, he/she may benefit from pain reduction and function improvement. PCN and PRF are known as non or minimally invasive procedures, therefore no full anaesthetic is needed and no overnight stay in the hospital is required. Neck bracing for three days is needed and gradually increasing neck loading in the next four weeks afterwards. Moreover, patients consenting to participate are not allowed to receive physical therapy during study participation and will have to return for longer follow ups and more often. Follow-up visits are scheduled three times

after treatment. Each visit will take approximately 30-40 minutes.

Both treatment groups have their own reported risks in terms of side effects/complications, however these are small in number, and mild and transient of nature. The majority of studies reported no significant complications related to PCN. PRF accounts as a safe treatment since the intent is specifically not to cause tissue injury. Therefore neurological side effects or complications with PRF are rarely mentioned.

Patients with insufficient relief of symptoms three months after treatment will be offered immediate and appropriate further pain management.

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

- Diagnosed with radiographically confirmed contained cervical disc herniation on MRI at one level
- Received a diagnostic block
- Failed conservative therapy during at least six weeks
- Radicular pain with or without neck pain, corresponding to herniated level
- VAS-100 mm pain score at least 50 mm or higher
- Patients have a stable drug regime

Exclusion criteria

- Contraindication for intervention with nucleoplasty or pulsed radio frequency
- Sequestered or extruded disc fragment, spondylolisthesis, vertebral fracture or spinal stenosis
- Uncovertebral or facet arthrosis
- Previous surgery or any type of infiltrations at the indicated cervical level
- Contained cervical disc herniation >1/3 spinal canal
- Radiographically confirmed loss of >30% disc height compared to adjacent cervical level
- Severe disc degeneration
- Unstable medical condition

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2012

Enrollment:	38
Type:	Actual

Ethics review

Approved WMO Date:	31-05-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL39783.015.12