

# Percutaneous plasma discectomy study

<b>Submission date</b> 10/04/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/04/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/01/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cervical radiculopathy (CR) is a common disorder of the nervous system characterized by dysfunction of a cervical spinal nerve, the roots of the nerve or both. When conservative treatment fails, surgical treatment is considered. However, it is associated with serious complications and a prolonged period of recovery. Currently, there is a trend in spinal surgery toward less invasive techniques. Nucleoplasty is the newest minimally invasive procedure for percutaneous disc decompression. To our knowledge, no studies have compared the relative harms and benefits of the treatments cervical percutaneous plasma discectomy and anterior cervical discectomy. Since the complications of open nucleotomy include a small risk of local inflammation, local pain and a longer period of recovery, it would be considered an important improvement if the same advantages of open nucleotomy could be achieved with percutaneous plasma discectomy as it is much less invasive. The aim of this study is to compare the clinical effects and cost-effectiveness of these two treatments in a group of patients with cervical radicular pain.

### Who can participate?

Patients aged between 18 and 65 with cervical radicular pain with an indication for surgery, who did not improve in at least 2 months of conventional treatment.

What does the study involve? Participants will be randomly allocated to undergo either percutaneous plasma discectomy or anterior cervical discectomy. Tests and questionnaires will be used to perform a complete assessment of pain and functioning at the beginning of the study and after 3 and 12 months.

### What are the possible benefits and risks of participating?

The two treatments are standard procedures in the participating treatment centres, so the patients will undergo no additional treatment and will not be exposed to any additional risks by participating in the study. The burden associated with participation is that participants will have to fill out a number of online questionnaires and will have to make three clinic visits to undergo additional tests.

### Where is the study run from?

The study will include patients from the Erasmus Medical Centre in Rotterdam, the Sint Franciscus Gasthuis Rotterdam and the Albert Schweitzer Ziekenhuis in Dordrecht.

When is the study starting and how long is it expected to run for?

The study will be open to enrol participants between April 2012 and April 2015. Assessments will continue for one year following the intervention.

Who is funding the study?

Erasmus Medical Center, Rotterdam, Netherlands.

Who is the main contact?

Prof. F.J.P.M. Huygen

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## Contact information

### Type(s)

Scientific

### Contact name

Dr F.J.P.M. Huygen

### Contact details

Erasmus Medical Center

University of Rotterdam

Centrumlocatie

T.A.V. Centrum voor Pijn geneeskunde

Gravendijkwal 230

Rotterdam

Netherlands

3015 CE

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NL32745.078.10

## Study information

### Scientific Title

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

### Study objectives

Current hypothesis as of 11/12/2013:

1. Percutaneous plasma discectomy is more effective than anterior cervical discectomy on pain, patient satisfaction/global perceived effect, functional status and health-related quality of life in

patients with cervical radicular pain caused by a contained soft disc herniation.

2. Percutaneous plasma discectomy leads to less morbidity, complications and medical costs compared to anterior cervical discectomy in patients with cervical radicular pain caused by a contained soft disc herniation.

Previous hypothesis:

1. Percutaneous plasma discectomy is more effective than anterior cervical discectomy and conservative treatment on pain, patient satisfaction / global perceived effect, functional status and health-related quality of life in patients with cervical radicular pain caused by a contained soft disc herniation.

2. Percutaneous plasma discectomy leads to less morbidity, complications and medical costs compared to anterior cervical discectomy in patients with cervical radicular pain caused by a contained soft disc herniation.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Erasmus Medical Centre Internal Ethics Board, 07/12/2010, ref: MEC-2010-277

Added 11/12/2013: amendment approved by the medical ethical committee of the Erasmus Medical Centre, 10/10/2013, ref: NL32745 078 V11\_METC191658

### **Study design**

Multicenter randomised controlled parallel-group study with two groups

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Cervical radicular pain of the lower cervical spine (C4-C7)

### **Interventions**

Technique anterior cervical discectomy

This operation will be performed by a neurosurgeon according to the standard guidelines of the Dutch Neurosurgeons Association

Technique percutaneous plasma discectomy

1. Review the ArthroCare Perc-DC SpineWand Instructions for Use, ArthroCare System 2000

Controller Users Manual and brochures prior to using the device.

2. The same physician will perform all study-related procedures.

3. The nucleoplasty procedure will be performed using a C-arm fluoroscope with image intensification.

4. 30 minutes pre-operative prophylaxis is intravenous given with 2 grams Kefsol.

5. Use an anterior-lateral discography approach and target the center of the disc during insertion of the access needle.

6. Confirm proper placement using AP and Lateral views

7. Re-position the green marker on the needle shaft down to skin level

8. Withdraw the stylet from the needle and insert the Perc-DC Wand under fluoroscopic guidance.

9. Using fluoroscopy, monitor the deployment of the Wand beyond the tip of the needle and secure the luer-lock onto the needle hub.

10. Confirm position of the Wand tip using AP and Lateral views.

11. Connect the Wand Cable to the Patient Cable. Align the dot at the base of each connector and directly insert the male into the female connector.

12. Secure the sterile cable onto the sterile field.

13. Verify proper placement of the tip of the Wand.

14. Set the Controller at Set Point 2 or 3 and depress Coag on the Foot Pedal for one-half second. If stimulation (movement) is observed, STOP, and reposition the Wand tip.

15. While holding the needle hub securely with one hand, grasp the Perc-DC Flange with the other hand. Depress Ablation on the Foot Pedal for 3 to 5 seconds while rotating the Flange 360 degrees in a back-and-forth motion.

16. To perform an additional ablation, retract the needle with the secured Wand 2 mm, using fluoroscopic guidance to confirm correct Wand deployment. Confirm new position of Wand tip using AP and Lateral views. Repeat steps 15 and 16.

17. After the Coblation Zone has been created, withdraw the Wand with the needle from the patient.

18. Clean the skin following standard procedure, and place a sterile dressing over the needle puncture site.

19. Apply a soft cervical neck brace immediately after the procedure for 48 hours.

20. The operated level, location of entry, and evaluation of the portal(s) will be documented.

#### Escape medication

Pain medication according to the WHO guideline.

On 11/12/2013 the following study arm was removed from this field as a result of a protocol amendment:

#### Conservative care

The conservative care will be performed by local physiotherapists in accordance with the guidelines of the Dutch Physiotherapy Association.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

Intensity of the pain, measured with a Visual analogue scale (VAS). The VAS is measured in millimetres (0-100, no pain most intensive pain). Measured pre and post intervention.

## **Secondary outcome measures**

1. Patient satisfaction/global perceived effect (online questionnaire)
2. Functional status (Muscle strength (MicroFet 2 Dynamometer), Physical activity (Upper Limb Activity Monitor), Sensibility (Quantitative Sensory Testing and DNIC) and online questionnaires)
3. Health-related quality of life (online questionnaire)
4. Morbidity (online questionnaire)
5. Complications (online questionnaire)
6. Medical costs (The cost analysis will be performed from a societal viewpoint in collaboration with the Institute for Medical Technology Assessment of the Erasmus University. Three categories of costs are distinguished:
  - 6.1. Direct costs within the healthcare
  - 6.2. Direct costs outside the healthcare system
  - 6.3. Indirect costs outside the healthcare

Measured pre and post intervention

## **Overall study start date**

01/04/2012

## **Completion date**

30/12/2016

## **Eligibility**

### **Key inclusion criteria**

1. Radicular pain of the lower cervical spine (C4 C7)
2. Complaints of radicular pain [Visual Analogue Scale (VAS) (0-100) at least 50] as a result of a contained soft disc hernia
3. With or without neck pain
4. Without improvement in at least 8 weeks of conservative therapy

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

150

### **Key exclusion criteria**

1. Age below 18 and above 65 years
2. Pregnancy
3. Anticoagulant drug therapy and/or disturbed coagulation
4. Infections/ tumours
5. Previous spinal surgery in cervical region
6. Extruded disc fragment; bony spurs; calcified disc

7. Herniation > 5 mm
8. Disc: maximal 50% loss of height
9. Neurodegenerative diseases, including lesions of the spinal cord
10. Lack of cooperation of the patient
11. Patients who are not able to complete the questionnaires, according to the referring doctor
12. Drugs/medication/ alcohol addiction
13. Serious psychopathology

**Date of first enrolment**

01/04/2012

**Date of final enrolment**

01/04/2015

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Erasmus Medical Center

Rotterdam

Netherlands

3015 CE

## **Sponsor information**

**Organisation**

Erasmus Medical Centre (Netherlands)

**Sponsor details**

c/o Dr. J.G. Groeneweg

University of Rotterdam

Centrumlocatie

T.A.V. Centrum voor Pijngeneeskunde

Gravendijkwal 230

Rotterdam

Netherlands

3015 CE

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.erasmusmc.nl/>

**ROR**

<https://ror.org/018906e22>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Erasmus Medisch Centrum

### **Alternative Name(s)**

Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Universities (academic only)

### **Location**

Netherlands

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration