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Percutaneous plasma discectomy study

Submission date
10/04/2012

Recruitment status
No longer recruiting

Registration date
26/04/2012

Overall study status
Completed

Last Edited
03/01/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Multicenter randomised controlled parallel-group study with two groups

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration