Percutaneous Radiofrequency Treatment of the Cervical Facet joints compared with Cervical Medial Branch block of the Facet Joints for Patients with Chronic Degenerative Neck pain : A Prospective Randomized Clinical Study

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To evaluate the effect of Radio Frequency treatment of the nerves innervating the cervical facet joints in patients with chronic degenerative neck pain.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON37554

Source
ToetsingOnline

Brief title
RFD of the cervical facet joints versus Cervical Medial Branch block.

Condition

- Joint disorders

Synonym
cervical facet degeneration, facet arthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cervical facet joint, degeneration, medial branch, radiofrequency treatment

Outcome measures

Primary outcome

The primary research question is to evaluate the extent of pain reduction

induced by RF treatment (RFD group) compared with the control group.

Following evaluation tools are used : Numeric Rating Scale, Global Perceived

Effect on Likert Scale.

Secondary outcome

Consumption of pain medication (MQS), Patient Specific Functional Scale,

Quality of life scale (RAND 36), Hospital Anxiety and Depression scale (HADS),

and Neck Disabilty Index (Dutch version).

Study description

Background summary

The facet joints are an important pain generator in chronic neck pain. The beneficial effect of radio frequency treatment (RFD) of the cervical facet joints has been described in a RCT in patients with Whiplash Associated Disorders. In patients with degenerative neck complaints a positive effect has been described in observational studies.In a retrospective study, performed by our research group, an effect of more than 50 % is reported. Given this positive effect performing a RCT of RFD in this patient population is indicated.

Study objective

To evaluate the effect of Radio Frequency treatment of the nerves innervating the cervical facet joints in patients with chronic degenerative neck pain.

Study design

Prospective, randomized, double blinded clinical trial.

Intervention

Patients with at least 3 months of neck pain without radiation to the arm will be
randomized in 2 groups. The first group (RFD group) will receive a RF treatment adjacent to the medial branch innervating the cervical facet joints.RF treatment is an accepted, extensively investigated and scientifically described method to interrupt pain nociception. The second group (Control group) will receive an injection of local anaesthetic (bupivacaine) near the cervical medial branch.This is a therapeutic treatment .The efficacy of this last treatment has been described in one Randomized Controlled Trial.

Study burden and risks

All patients will undergo a physical examination before and 6 weeks after the intervention; this will be repeated at 3 and 6 months if abnormalities are observed. At each of these time points the patients will receive questionnaires to fill out.
The risks of the interventions are negligible and the procedures are well tolerated. A puncture of a blood vessel is possible, diagnosed by injection of contrast, for which repositioning of the needle is needed. Should accidental intravascular injection of local anesthetic occur, the dose used is low and reports show that intravascular injection of Bupivacaïne 2,5 mg does not pose clinical problems. The dura can be punctured; as a consequence contrast will flow in the cerebrospinal fluid. The procedure will be stopped and repeated after a few days. In theory a lesion of the nerve root is possible, but the needles are designed to avoid this and the procedure always takes place with fluoroscopic control. This complication has not been reported in more than 10 years. Up till now, a transient pain is occasionally described after the RF treatment. No hypesthesia or motor complications were reported. Allergic reaction to local anaesthetic or contrast agent is possible, but if known (part of the history taking) is an exlusion criterion for the interventions.

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

1) 1) Patient*s age > 25 year
2) Signs of degeneration on lateral X-ray
3) Cervical facets to be treated between C2 and C7
4) Pain for at least 3 months and conservative treatment prior to referral to the painclinic; medication (paracetamol, NSAID*s) and/or physical therapy
5) Neck pain NRS score * 5

Exclusion criteria

1) Radiation beyond the shoulder/radiculair pain
2) Shoulder pain/pathology
3) The complaints are directly related to traumatic event e.g. Whiplash (WAD)
4) Patient is pregnant, or pregnancy is suspected
5) Patient has a cardiac pacemaker, automatic defibrillator or any leads in the neck area
6) Allergy to contrast media or drugs to be used in the procedure
7) History of anterior fusion at the cervical level to be treated

8) Patient is simultaneously participating in another device or drug study related to cervical pain.
9) Patient has a spinal fracture, tumor or infection.
10) Patient has a central cord lesion in the cervical spine
11) Neurologic deficit
12) Evidence of disc herniation (extruded, sequestered on MRI imaging)

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):	07-02-2013
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT12
CCMO	NL38863.068.12