Lateral C1-2 Joint Pulsed Radiofrequency Application in the treatment of Cervicogenic Headache

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The primary objective in this study is to compare the effectiveness of lateral C1-2 pulsed radiofrequency application (LPRF) in comparison with conventional C3-5 facet denervation (MBRF) in patients with clinically defined cervicogenic headache.

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

Summary

ID

NL-OMON34846

Source
ToetsingOnline

Brief title
Lateral C1-2 Joint PRF: A RCT

Condition

- Joint disorders
- Headaches

Synonym
Cervical headache, Headache from the neck

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atlanto-axial joint injection, Cervicogenic Headache, Lateral C1-2 Joint injection, Pulsed radiofrequency

Outcome measures

Primary outcome

The primary study parameter is the proportion of patients that experience more

than 50% pain relief at 1 month after either procedure. Numerical rating scale

(NRS) scores for pain will be recored at baseline and at each follow-up visit.

Secondary objectives include the rescue rates (proportion of patients with less

than 50% pain relief requiring additional treatment).

Secondary outcome

The secondary outcomes in this study includes

1. The proportion of patients that require additional treatment 1 month after

the first procedure

2. The NRS (Numerical Rating Scale) scores at 1, 2 and 3 moth intervals using

the PGIC (Patient Global Impression of Change) .

3. Scores from 4 questionnaires

a. SF-36 (Quality of Life)

b. HIT-6 (Headache Impact)

c. NDI (Neck Disability Index)

d. MOS Sleep Scale (Medical Outcomes Study Sleep

Scale)

Study description

Background summary

Cervicogenic headache is pain referred to the head from a source in the cervical spine. The prevalence of cervicogenic headache has been estimated up to 4.1% in the general population and as high as 17.5% among patients with severe headaches. The prevalence is as high as 53% in patients with headache after whiplash. Currently, no drugs are effective for cervicogenic headache.

The most extensively studied and widely accepted treatment for cervicogenic headache is percutaneous radiofrequency neurotomy of the medial branches (conventional C3-5 medial branch radiofrequency (MBRF) that supply the affected cervical zygapophysial joints. Reported success rates in the literature for this standard technique, which is our control group, range from 33% to 50% at 2-3 months.

Atlanto-axial joint (C1-2) injections have also identified the lateral atlanto-axial joint as a source of pain in patients with cervicogenic headache. In a retrospective study with 86 patients (Halim and Chua et al. Long Term Pain Relief in patients with Cervicogenic Headaches after Pulsed Radiofrequency Application into the Lateral Atlanto-Axial (C1-2) Joint using an Antero-lateral Approach. Accepted in Pain Practice and awaiting publication), pulsed radiofrequency (PRF) application into the lateral C1-2 joint of cervicogenic headache patients produced long term pain relief. The proportion of patients who had *50% pain relief at 2 months, 6 months and 1 year were 50% (43/86), 50% (43/86) and 44.2% (38/86) respectively.

In a prospective trial, we aim to determine the effectiveness of lateral C1-2 joint PRF application (LPRF=study group) versus conventional C3-5 facet denervation (MBRF=control group) in patients who have clinically defined cervicogenic headache.

Study objective

The primary objective in this study is to compare the effectiveness of lateral C1-2 pulsed radiofrequency application (LPRF) in comparison with conventional C3-5 facet denervation (MBRF) in patients with clinically defined cervicogenic headache.

Study design

The study is designed as a randomised single-blind clinical trial. Patients aged 18 years and above with cervicogenic headache of at least 3 months duration are eligible for inclusion. The patients will be given both oral and

written information about the procedures and baseline evaluation will only be performed after informed consent is given. The diagnostic criteria from Antonaci, which had been adapted from the original Sjastaad*s criteria will be used to define possible and probable cervicogenic headache. Only patients with at least possible cervicogenic headache will be included into the study. The included patients will then be randomized into the 2 treatment groups. For both treatment groups LPRF and MBRF, if there is significant pain relief after 1 month, the patient is followed up for another 2 months. If there is less than 50% pain relief at 1 month, the patient will undergo additional treatment and is then followed up for another 2 months. The patients will be given questionnaires (PGIC, SF-36, HIT-6, Neck Disability Index and MOS Sleep Scale) at the end of the consult that require a maximum of 20 min to complete. The inclusion period of the study is from June 2010 till June 2011. 70 patients will be recruited and treated entirely at St Anna Hospital Outpatient Pain Management Centre in Geldrop and will be followed up for a total of 3 months in this study.

Intervention

In this RCT, the effectiveness of lateral C1/2 joint pulsed radiofrequency application (LPRF) is compared to conventional C3-5 facet denervation (MBRF). The 2 procedures differs in several aspects.

LPRF targets the lateral atlanto-axial joint (C1/2 joint) and is done with the patient lying supine. Only one needle puncture is required (usually just below the angle of the mandible) and the needle is directed under fluroscopic guidance. No local anaesthetic is given into the joint due to possible extravasation risks and side effects of ataxia. Pulsed radiofrequency application does not create an actual thermal lesion but its effects are believed to be a result of electrical fields generated at the needle tip and hence has no or little risk of causing permanent neural damages.

MBRF is the conventional technique used to treat cervical facet joint pain and is used in this case to treat cerrvicogenic headache which is a complication of the primary facet joint pain. it is performed also with the patient supine but requires 3 needle punctures at the lateral aspect of the neck. The needles are directed fluroscopically to the facetal pillars from C3-5. Local anaesthetics have to be given prior to the radiofrequency lesioning as radiofrequency denervation creates an actual thermal lesion as a result of the temperature generated during the 90 seconds of probe activation. The possibility of causing long lasting neural damages are inherent but rare in the procedure. However, this technique is considered standard treatment for neck pain around the world as it is relatively safe if standard stimulation protocols are adhered to.

Complications are rare in both procedures. in 250 LPRFs performed in St Anna Hospital, there has been only 1 case of a patient developing a sudden but temporary worsening of her headache which lasted 1 day. In C3-5 facet

deneravtion (MBRF), complications are rare as stated in available literature. The incidence of inadvertent intravascular penetration for medial branch blocks at cervical spinal level was reported to be 3.9%, comparable with the incidence at lumbar level (3.7%). Other potential complications of facet joint interventions are related to needle placement; they include dural puncture, spinal cord trauma, spinal anesthesia, neural trauma, radiation exposure, facet capsule rupture and hematoma formation. After MBRF treatment, postoperative burning pain is regularly reported. This pain disappears after 1 to 3 weeks.

Study burden and risks

The patient will take a maximum of 20 min to complete the 4 specified questionnaires. Otherwise, the procedures performed are entirely consistent with the routine treatment in St Anna Hospital, Geldrop.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Male and female patients who are 18 years or more of age.
Patients with a history of chronic, function-limiting cervicogenic headache of at least 3 months duration.
Patients who are able to provide voluntary, written informed consent to participate in this evaluation.
Patients willing to return for follow-ups.
Patients without a history of recent surgical procedures (i.e. within the last 6 months)

Exclusion criteria

Patients with uncontrolled major depression or psychiatric disorders.
Patients with recent history of heavy opioid usage, chronic alcoholism or substance abuse.
Patients with acute or uncontrolled medical illness, malignancy or poorly controlled epilepsy.
Patients with chronic severe conditions that could interfere with the interpretations of the outcome assessments.
Patients with fibromylagia or painful syndromes of unknown origin or associated with diffuse pains.
Female patients who are pregnant or lactating,
Patients with histories of adverse reactions to local anesthetic or steroids
Patients with anatomical abnormalities on cervical spine X-ray that may result in technical difficulties for blocks

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-01-2010
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO Date:	23-06-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL30922.091.09