A Randomised Placebo-Controlled Double-blinded High Cervical Epidural Neurostimulation Trial in patients with Intractable Cervicogenic Headache

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The primary objective in this study is to evaluate effectiveness of optimized high cervical epidural neurostimulation against placebo-stimulation in patients with intractable cervicogenic headache in a neurostimulation trial.

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

Summary

ID

NL-OMON35036

Source
ToetsingOnline

Brief title
High Cervical Neurostimulation in Intractable Cervicogenic Headache

Condition

- Joint disorders
- Headaches

Synonym
Pesistant Headache associated with Chronic Neck Pain, Resistant Head and Neck Pain

Research involving
Human

Sponsors and support

Primary sponsor: Anesthesiologie, Pijn en Palliatieve Geneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: High Cervical Epidural Neurostimulation, Intractable Cervicogenic Headache

Outcome measures

Primary outcome

The main study parameter is the mean daily VAS (visual analogue scale) pain scores during the 4 days of test-stimulation versus the 4 days of placebo-stimulation. Objective parameters in the form of QST measurements will also be obtained.

Secondary outcome

Secondary parameters includes:

1. QST measurements over:

a. Thenar eminence on the hand

b. Suboccipital area (2 cm inferior and lateral to the occipital protuberance)

c. V2-3 dermatome (over the masseter muscle)

2. Qualitiy of Life using the SF-12 which will be applied at baseline assessment and at the last consult after the trial.

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. For some patients with cervicogenic headaches, the current available treatments such as cervical facet denervation, greater occipital nerve blocks, anterior cervical vertebral fusion, greater occipital nerve stimulation have limited success both in terms of efficacy and duration of action. Incorporating the definition of Goadsby and colleagues, we define these group of patients as having *Intractable cervicogenic headache*. The convergence of the cervical and trigeminal afferents in the trigeminocervical nucleus allows the bidirectional transmission of pain signals between the neck and the trigeminal sensory receptive fields of the face and head. For these patients, it is this transmission junction that we should concentrate the efforts of our treatment. High cervical epidural neurostimulation has been performed for more than 10 years for a variety of indications. Safety and technical aspects of the procedure has been well reported in previous instances of cervical epidural stimulation for severe Raynaud*s disease, failed neck surgery syndrome and in patients with head and neck tumors.

Study objective

The primary objective in this study is to evaluate effectiveness of optimized high cervical epidural neurostimulation against placebo-stimulation in patients with intractable cervicogenic headache in a neurostimulation trial.

Study design

The study is designed as a randomized placebo-controlled double-blind clinical trial. Patients aged 18 years and above with intractable cervicogenic headache of at least 12 months duration are screened psychologically and degree of disability assessed. The trial period begins with an optimization phase of 5 days to obtain each patient*s optimal neurostimulation settings. This is followed by a stimulation-off interval and then proceeding on to a randomized crossover phase, with each patient acting as his own control. The trial for each patient concludes after the last QST (at the end of the 2nd stimulation block).

Intervention

High Cervical Epidural Neurostimulation

We describe the standard approach to cervical epidural lead insertion. After local anaesthesia with Lignocaine 1%, the epidural space will be reached with a 14-G Touhy needle at the level Thoracic 2/3 via a inter-laminar approach. Loss

of resistance to saline (NaCl 0.9%) indicates epidural placement of the Touhy needle-tip. Fluoroscopic imaging will be performed in two planes (Lateral and antero-posterior). A 33-cm octapolar electrode with 30 mm electrode distance, 6 mm electrode spacing and 1.3 mm diameter will be used. The electrode will be directed cranially and slowly pushed to the upper cervical region of C2. The final position will often be obstructed by the inferior margin of the occipital bone (See Figure 2). Test stimulation will be performed in the operation room, but that is by no means the end-point of our optimization process. In our experience, pain relief and paraesthesia covering the whole painful region in the neck, the occipital, and even the fronto-parietal regions can sometimes be achieved immediately. But our hypothesis is that effect of neurostimulation on the trigeminal nucleus caudalis will occur over days and therefore the rationale for an optimization period of 5 days duration. Initial stimulation settings will range from: amplitude 1.0-2.0V, frequency 100-200 Hz, impulse duration 200-400 ms.

Study burden and risks

The patient will take a maximum of 20 min to complete the 4 specified questionnaires mailed to him prior to his appointment. Each patient has to undergo 3 QST measurements and each session takes 60 min to complete.

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. Male and female patients who are 18 years or more of age.
2. Patients with a history of chronic, function-limiting cervicogenic headache of at least 12 months duration.
3. Patients who are able to provide voluntary, written informed consent to participate in this evaluation.
4. Patients willing to return for follow-ups.
5. Patients without a history of recent surgical procedures (i.e. within the last 6 months)

Exclusion criteria

1. Patients with uncontrolled major depression or psychiatric disorders.
2. Patients with recent history of heavy opioid usage, chronic alcoholism or substance abuse.
3. Patients with acute or uncontrolled medical illness, malignancy or poorly controlled epilepsy.
4. Patients with chronic severe conditions that could interfere with the interpretations of the outcome assessments.
5. Patients with fibromylagia or painful syndromes of unknown origin or associated with diffuse pains.
6. Female patients who are pregnant or lactating,
7. Patients with histories of adverse reactions to local anesthetic
8. 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
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2010
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-06-2010
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	NL31135.091.10