Treatment of central pain syndromes by caloric vestibular stimulation

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Objective of the study: With this pilot study we attempt to explore the possibility to treat patients suffering from intractable neuropathic pain with CVS

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34997

Source
ToetsingOnline

Brief title
CVS in central pain syndromes

Condition

- Other condition
- Mental impairment disorders

Synonym
nerve pain, neuralgia

Health condition

centrale pijnklachten

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: body ownership and embodiment, central pain, Non-invasive, vestibular system

Outcome measures

Primary outcome

Primary study parameters/outcome of the study: Changes in NRS pain scores as a result of the CVS treatment

Secondary outcome

Secundary study parameters/outcome of the study: Immediately following and a week after CVS treatment patients will be asked about the experiences, both positive and negative, they attribute to the CVS treatment

Study description

Background summary

Background of the study: Central pain is caused by a dysfunction of the brain and/or the spinal cord. The exact mechanism is unclear but usually there is an incongruence between anticipated and actual somatosensory input. Treatment of these patients is very complicated. Due to the widespread *neuropathic* pain complaints combined with a treatment resistancy, this will lead to pain *suffering* in both patients as well as relatives.
Recently, a non-invasive approach called caloric vestibular stimulation (CVS) has been described and evaluated in these patients. CVS directly activates a complex network of areas predominantly in the temporo-insular and temporo-parietal cortex of both hemispheres. The activated areas receive multisensory information (vestibular, visual, proprioceptive, tactile) and are thought to be involved in body ownership and embodiment.
The effects of CVS on pain appear to be dramatic with a long lasting effect in a number of patients. Studying the effects of this approach might lead to a new way of treating these patients and these pain syndromes.

Study design: Pain scores of patients will be obtained before, immediately following and a week after a single CVS treatment.
Study population: For this pilot, six adult patients with treatment-resistant central neuropathic pain in the upper body on the non-dominant side will be recruited in the Pain Center of UMC St Radboud. Patients will have to provide written informed consent. Excluded from this pilot study are patients with the following conditions: Other neurological disorders causing pain, significant cardiac or respiratory disease (inadequately treated hypertension), ear disease such as a perforated ear drum or otitis media/externa, vestibular disease or significant motion sickness, or pregnancy.

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Intervention

Intervention: The patient will be positioned in a supine position with head at a 30° elevated angle. Patients will receive ear canal irrigation with ice water (~4°C) on the dominant side (right ear for right handed people). The irrigation (~30 ml) will continue until there are demonstrable signs of nystagmus and reports of vertigo, but at least 30 s.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: CVS with ice water is a safe technique that is normally used for diagnostic purposes. The strong stimulation may acutely result in a transient dizziness and nausea. The anticipated benefit is a much longer lasting relieve of the neuropathic pain. The cold temperature of the

fluid might be uncomfortable.

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

- Neuropathic pain in the non-dominant side
- Resistant to or not suitable for other treatments

Exclusion criteria

- Other neurological disorders causing pain.

- Significant cardiac or respiratory disease (inadequately treated hypertension)
- Ear disease such as a perforated ear drum or otitis media/externa
- Vestibular disease or significant motion sickness
- Pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2012
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	12-01-2012
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	NL31513.091.10