Determining the efficacy of chordotomy using laser evoked potentials: a pilot study

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Primary Objective: Evaluate the functional integrity of the nociceptive system after percutaneous cervical chordotomy using Laser Evoked Potentials Secondary Objective(s): change in opioid consumption after percutaneous cervical chordotomy using a...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON40920

Source
ToetsingOnline

Brief title
Chordo study

Condition

- Spinal cord and nerve root disorders

Synonym
chronic intractable unilateral pain

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chordotomy, diode laser, laser evoked potential, LEP

Outcome measures

Primary outcome

Laser Evoked Potentials before PCC: N2P2 amplitude, N2 and P2 latency

Laser Evoked Potentials after PCC: N2P2 amplitude, N2 and P2 latency

Secondary outcome

Opioid consumption before PCC (mg/day) calculated in morphine equivalents

Opioid consumption after PCC (mg/day) calculated in morphine equivalents

Study description

Background summary

Percutaneous cervical chordotomy (PCC) is a neurolytic technique which destroys nociceptive pathways in the spinal cord [Mullan et al, 1963]. PCC is often used to control intractable unilateral pain due to cancer and compression of surrounding neuronal tissues. It is particularly effective in managing severe chest pain, known as the costopleural syndrome, accompanying malignant mesothelioma. This method is described to exert significant pain relief in 83% of patients with pleural mesothelioma [Jackson et al, 1999]. The degree of effectiveness is mainly based on the extent in which opioïd intake decreases after the procedure, which seems rather insufficient to objectively determine spinothalamic tract function. Therefore, a quantifiable method to evaluate the functional integrity of the nociceptive system after PCC, might be useful. Laser stimuli can be applied to selectively activate pain receptors in the skin, and generate an afferent volley in poorly myelinated Aδ and unmyelinated C fibers that, upon arrival to the central nervous system, can be recorded at the vertex as laser-evoked-potentials (LEPs) [Schestatsky et al, 2007]. In healthy subjects it shows a negative-positive complex, comprising a N2 and P2 component, in a time window between 175-500ms after stimulation [Treede et al, 2003]. These waveforms reflect nociceptive responses and correlates with the functional integrity of the spinothalamic tract. Pathological LEP reductions occur for certain lesions of the peripheral nerve, plexus, root or spinal cord [Treede et al, 2003]. Therefore, LEPs can be useful for objectively confirming impairment of nociceptive pathways. The aim of this study is to assess if LEPs

can reliably be used to determine the efficacy of PCC. Furthermore, the change in opioid consumption will be evaluated using a pain diary.

Study objective

Primary Objective: Evaluate the functional integrity of the nociceptive system after percutaneous cervical chordotomy using Laser Evoked Potentials

Secondary Objective(s): change in opioid consumption after percutaneous cervical chordotomy using a pain diary

Study design

This study is a prospective, observational, mono-center pilot-study. 5 study subjects will participate in this pilot study at the outpatient Neurophysiology clinic of the St. Antonius Hospital Nieuwegein. Subjects will be screened upon the inclusion and exclusion criterion, consented, and enrolled in the study from November 2014 - November 2015.

Intervention

Laser stimulation session
Cutaneous heat stimuli are delivered by a 980-nm diode laser (Biolitec, Ceram Optec, Bonn, Germany) to the blackened dorsum of the right and left hand (C6 dermatome). Blackening of the skin is performed to rule out bias by differences in skin pigmentation. Laser intensity is set at 1.0-2.5W (10-25 mJ/mm2), duration of the stimuli is set at 50 msec, with a laser beam spotsize of 5 mm2. The stimulus intensity will be adjusted to evoke a clear pinprick sensation (before the PCC is performed). Interstimulus duration randomly varies between 5 and 10 sec to assure reorientation of attention to an unexpected stimulus. 10 laser stimulations will be adminstrated. In the second stimulation session (after PCC) the same laser settings will be used. Our study group is experienced in using this non-invasive device [MEC ID: R-06.38A, GOV ID: NL14786.100.06; Korenromp et al, 2012].

Recording and Processing
Electroencephalography (EEG) recordings will be made to measure brain activity following laser stimulation. EEG epochs recorded 200 msec before and 800 msec after the onset of each stimulus.

Study burden and risks

Risks during participation in this study are negligible. Stimulation of Aδ nerve fibers testing using 980nm diode laser stimulation might induce a pinprick feeling in participants and some mild skin redness which will resolve

spontaneously.

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

• Unilateral intractable pain
• Eligible for Percutaneous Cervical Chordotomy
• Informed consent
• >18 years

Exclusion criteria

• Recent invasive neurolytic treatment
• Dermal lesions at the site of stimulation (i.e. psoriasis, ulcera, infection)
• Subject currently has an active implantable device including ICD/pacemaker

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	980 nm diode laser
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	20-01-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL50921.100.14