The Neurophysiologic monitoring of pain: the laser evoked potential (LEP) ESES therapy

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This study will evaluate several LEP characteristics before and during pain alleviation methods.Does pain treatment affect VAS scores, noted by the subject before and after a set of applied stimuli.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32385

Source
ToetsingOnline

Brief title
LEP-Ther

Condition

- Other condition

Synonym
Failed Back Surgery Syndrome (FBSS)

Health condition

chronische pijnsyndromen

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Innovatiefonds en Maatschap Anesthesiologie St. Antonius Ziekenhuis en declaratie overige kosten i.v.m uitvoering onderzoek bij afdeling KNF

Intervention

Keyword: evoked potential, neuromodulation, pain, SCS

Outcome measures

Primary outcome

Laser evoked potential: Amplitude of N2 and P2 peaks of laser evoked potential (LEP), AUC (area under curve) of LEP between 175 - 500 ms after stimulus, latencies of N2 and P2 peaks of LEP during HF, LF stimulation and without stimulation.

VAS: After each series of randomly applied stimuli, the participant is asked to estimate their subjective measurement of pain intensity on a Visual Analog Scale (VAS), these scores are compared to the VAS scores as noted in a pain diary a week before these tests.

Secondary outcome

not applicable

Study description

Background summary

Myelinated Ad and unmyelinated C fibers are the primary nociceptive afferents of the skin. Melzack and Wall (1965) have suggested an inhibition of nociceptive processing within the spinal dorsal horn and/or thalamus by simultaneous activation of tactile afferents mediating touch (gate-control theory). Based on this concept, patients with chronic pain are being invasively

treated by electrical stimulation of tactile Ab afferents within peripheral/cranial nerves or the dorsal columns/roots of the spinal cord. Furthermore, ESES therapy is being used as an afferent stimulation technique for pain alleviation. Although these neuromodulatory methods have been applied for decades, their clinical application and indication are controversial because the supposed antinociceptive effect in humans has not been objectively proven so far. A major reason for the limited progress on the knowledge on nociception was the lack of a quantifiable method to selectively activate Ad and C-fibers with no or low concurrent activation of other sensory modalities. Infrared laser stimulation of the skin has been shown to selectively activate Ad and C fibres, being followed by a late evoked potential at the vertex (Laser Evoked Potential (LEP), which consists of a N2 and P2 component in a time window between 175 and 500 ms), mainly due to Ad stimulation and an ultralate evoked potential (>800 ms) caused by C fiber stimulation. Late LEPs are considered to be closely related to the perception of pain and a strong relationship between the amplitude of the LEP and subjective pain rating has been found.
Therefore, determining late LEP characteristics may be an objective way to evaluate the effects of invasive (spinal cord stimulation) pain alleviation methods.

Study objective

This study will evaluate several LEP characteristics before and during pain alleviation methods.
Does pain treatment affect VAS scores, noted by the subject before and after a set of applied stimuli.

Study design

Observational study of FBSS patients who recently received a SCS device.

Study burden and risks

Patients enrolling in this study are asked to participate during 60-90 minutes. The test will be planned directly after a regularly set appointment at a pain consultant. Patients will document their measurements of subjective pain perception (VAS) in a pain diary, during 1 week before this test.
They will be connected to an EEG-recorder. Laser stimuli will be applied to the dorsum of the foot, which may cause transient redness which will resolve within days. Other risks associated with this study are negligible.
Different pain treatment modalities are being widely used, in spite of lack of evidence that support clinical usefulness. Benefit is in expanding knowledge of objective evaluation of pain treatment modalities.

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

Patients with FBSS and have received a SCS recently.
Age between 18-70 years

Exclusion criteria

Neurological or psychiatrisch disease
Diabetes Mellitus (DM)
Extensive vascular disease
Dermatological disease at the site of planned applied stimuli

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2008
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Diode laser
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	13-05-2008
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	NL21536.100.08