Habituation or sensitization effects of repetitive nociceptive stimuli measured with cortical event related potentials in patients with and without chronic pain after a lumpectomy or mastectomy and an axillary lymph node dissection.

Published: 28-12-2009
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Primary Objective: to investigate the cortical event related related potentials to repetitive nociceptive stimuli in patients with chronic pain compared to patients without pain.Secondary Objectives:to investigate the relation between DNIC response...

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

Summary

ID

NL-OMON32895

Source
ToetsingOnline

Brief title
Cortical plasticity

Condition

- Other condition

Synonym
Generalized hyperalgesia; Chronic pain

Health condition

Chronische pijn

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: Chronic pain, Electroencephalogram, Habituation, Sensitization

Outcome measures

Primary outcome

N1-P2 peak-to-peak and P300 amplitudes in the event related potentials (EEG).

Secondary outcome

1. The quantification of DNIC response 2. The quantification of the subjective intensity of pain 3. The quantification of the nature of pain 4. Baseline parameters: date of birth, date of surgery, treatment technique, medication intake, duration of pain suffering, medical co-morbidity (neurological diseases, psychiatric diseases or diabetes).

Study description

Background summary

Chronic neuropathic pain is a major problem since it is difficult to treat and the understanding of the underlying neurobiology is sparse. Chronic pain is accompanied with hyperalgesia, an increased pain sensitivity. Long-term potentiation (LTP) at synapses of nociceptive nerve fibers is a proposed cellular mechanism underlying some forms of hyperalgesia, and is believed to be one of the key mechanisms underlying chronic pain. A decrease in pain thresholds out of the stimulated and segmental area are an indication for generalized hyperalgesia. A state of generalized hyperalgesia would at least

suggest involvement of supraspinal areas in the context of LTP induction.

Study objective

Primary Objective:
to investigate the cortical event related related potentials to repetitive nociceptive stimuli in patients with chronic pain compared to patients without pain.

Secondary Objectives:
to investigate the relation between DNIC response and the response on repetitive nociceptive stimuli in both groups, measured by event related potentials in the electroencephalogram.

to investigate the relations between the subjective intensity of pain and the response on repetitive nociceptive stimuli in patients with chronic pain, measured by event related potentials in the electroencephalogram.

to investigate the relations between the nature of pain and the response on repetitive nociceptive stimuli in patients with chronic pain, measured by event related potentials in the electroencephalogram.

Study design

This is an observational study, based on a cross-sectional repeated measures design in a patientgroup and controlgroup.

Study burden and risks

not applicable

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 after lumpectomy or mastecomy and an axillary lymph node dissection; 1 to 3 years post OK
Patients with pain presented longer than 3 months, will be included in de chronic pain group
Aged 18 - 65 years
Women

Exclusion criteria

Actual presence of (breast)cancer or metastases.
Presence or history of neurological (other than chronic pain) or major psychiatric diseases.
Regular intake of medication affecting potentially brain function or EEG signal.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	28-12-2009
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	NL30189.091.09