Characterization of nociceptive perturbation and threshold tracking methods.

Gepubliceerd: 24-06-2011 Laatst bijgewerkt: 19-03-2025

Change of nociceptive thresholds.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22734

Bron
Nationaal Trial Register

Aandoening

Pain, heterotopic noxious control stimulation, electrocutaneous stimulation, detection threshold, conditioned pain modulation

Ondersteuning

Primaire sponsor: University of Twente
Overige ondersteuning: This research is supported by the Dutch Technology Foundation STW, which is part of the Netherlands Organisation for Scientific Research (NWO) and partly funded by the Ministry of Economic Affairs, Agriculture and Innovation.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sensation thresholds over time and the ratio felt:not-felt stimuli.

Toelichting onderzoek

Achtergrond van het onderzoek

Persisting or chronic pain after surgical interventions is a frequently occurring problem. Even minor surgical interventions may lead to postoperative chronic pain development. Chronic pain severely restricts an individual?s quality of life, but also increases costs of global health care and absenteeism at work.

Mechanisms involved in chronic pain development may lie within ascending and/or descending pathways of the nociceptive system. Sensitizing effects caused by ascending mechanisms are normally counteracted by inhibiting effects of descending mechanisms. An imbalance between both pathways increases the risk of chronic pain development. Observation and identification of the state of these nociceptive pathways might provide information for optimization of pain management.

The sensitivity of mechanisms in the ascending pathway is reflected in psychophysical nociceptive thresholds, estimated using electrical stimulation of the skin (e.g. a decrease in nociceptive threshold indicates hyperalgesia). Different stimulus properties (e.g. the number of electrical pulses) are known to activate these mechanisms differently and result in different thresholds. Therefore, it is expected that simultaneous estimation of multiple thresholds reveal additional phenomena, enabling a more detailed observation and modelling of ascending nociceptive processing.

The activation of descending inhibiting mechanisms normally is proportional to the intensity of nociceptive input (i.e. the ?pain inhibits pain? phenomenon). The dynamics of the consequent threshold changes are still unknown, but may contain important information for discrimination between ascending and descending mechanism behaviour. Tracking nociceptive thresholds during well controlled nociceptive perturbations would be a first step to develop a method for independent identification of the state of both pathways.

Objective:

The purpose of this study is to obtain information for the design of a method to measure the behaviour of the ascending and descending pathways of the nociceptive system. Simultaneous tracking of multiple psychophysical sensation thresholds before, during and after patterns of (multilevel) thermal perturbations will be performed to:

1. Compare precision and efficiency of available algorithms for tracking of multiple thresholds;

2. Observe dynamic changes of thresholds induced by nociceptive perturbations;

3. Study how the number of simultaneously tracked thresholds affects the observability of dynamic changes in the nociceptive system;

4. Assess measured thresholds from different electrical stimulus properties;

5. Study the effect of temporal nociceptive perturbation patterns on the time course of tracked thresholds;

6. Study the effect of multilevel nociceptive perturbations on the time course of tracked thresholds.

Study design:

This study consists of six experiments:

1. Compare precision and efficiency of available algorithms for tracking of multiple threshold; quasi-experimental one group pretest-posttest study;

2. Observe dynamic changes of thresholds induced by nociceptive perturbations; experimental cross-over study;

3. Study how the number of simultaneously tracked thresholds affects the observability of dynamic changes in the nociceptive system; quasi-experimental one group pretest-posttest study;

4. Assess measured thresholds from different electrical stimulus properties; explorative longitudinal / one group pretest-posttest study;

5. Study the effect of temporal nociceptive perturbation patterns on the time course of tracked thresholds; experimental one-way repeated measures design;

6. Study the effect of multilevel nociceptive perturbations on the time course of tracked thresholds; experimental one-way repeated measures design.

Study population:

165 healthy volunteers.

Main study parameters/endpoints: The main parameters are:

Experiment 1: Estimation method (ascending method or random stimulus method);

Experiment 2: Perturbation method (Perturbation temperature);

Experiment 3: Number of nociceptive thresholds;

Experiment 4: Stimulus settings (number of pulses, inter-pulse interval, pulse width);

Experiment 5: Temporal nociceptive perturbations;

Experiment 6: Multilevel nociceptive perturbations

Doel van het onderzoek

Change of nociceptive thresholds.

Onderzoeksopzet

Experiments last between approximately 1 and 2 hours.

Onderzoeksproduct en/of interventie

Experiment 1 will take approximately 50-60 minutes and includes a cold pressor task lasting for a maximum time of three minutes. Experiment 2 will take approximately 2 hours and includes two cold pressor tasks lasting for a maximum time of two minutes each. Experiment 3 will take approximately 50-60 minutes and includes a cold pressor task lasting for a maximum time of 2 minutes. Experiment 4 will take place on two consecutive days and each day will take approximately 50-60 minutes. Moreover, experiment 4 contains two cold pressor tasks (one at each day) lasting for a maximum time of 2 minutes. Experiment 5 and 6 will take approximately 50-60 minutes and include two cold pressor tasks, each lasting for a maximum time of two minutes.

Psychophysical thresholds are determined using electrical stimulation. A single electrode is placed on a fourth between the distal end of the ulna and proximal end of the radius of the left arm and may cause mild skin irritation, which disappears within 30 minutes after removal. The cold pressor task is known to may cause a subject to faint. The maximum allowed time for this task is fixed such that the chance of a subject to faint is minimal. Subjects are always allowed to remove their hand from the water.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18 years and older;

2. Legally competent;

3. Able to communicate;

4. Cognitively competent;

5. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Diabetes;

3. MS;

4. HIV/AIDS;

5. Not able to deal with used research methods;

6. No compliance of instructions;

7. Loss of somatosensory function;

8. Deviating perception of pain;

9. Prolonged pain during the last three months;

10. Momentary pain complaints;

11. Fatigue;

12. Fibromyalgia.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	06-06-2012
Aantal proefpersonen:	165
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39755
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2820
NTR-old	NTR2961
CCMO	NL35175.044.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39755

Resultaten

Samenvatting resultaten
N/A