

Exploration of the effects of HFS-induced secondary hyperalgesia on the NDT-EP method

Gepubliceerd: 14-09-2021 Laatste bijgewerkt: 18-08-2022

The research is of exploratory nature and therefore does not have hypotheses

| | |
|-----------------------------|-----------------------|
| Ethische beoordeling | Positief advies |
| Status | Werving gestart |
| Type aandoening | - |
| Onderzoekstype | Interventie onderzoek |

Samenvatting

ID

NL-OMON25830

Bron

Nationaal Trial Register

Verkorte titel

NDT-EP + HFS

Aandoening

None

Ondersteuning

Primaire sponsor: University of Twente

Overige ondersteuning: Dutch Research Council (NWO) through the NeuroCIMT research program (P14-12, project 2)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(1) Nociceptive Detection Thresholds (NDTs)

(2) EEG signals

(3) Numerical Rating Scale to mechanical punctate stimulation

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic pain often results from disturbed processes in the central nervous system. Once chronic pain is established, treatment is relatively ineffective, with – at best – one patient in three or four achieving 50% pain intensity reduction. Early detection and therapeutic action would mean better treatment outcome and less clinical efforts per patient, but appropriate diagnostic tools are lacking. An increased sensitivity to noxious stimuli is widely recognized as a key factor in chronic pain development. Noxious stimuli are processed by neural mechanisms at several stages in the ascending pathway from periphery to brain, into a conscious pain experience. As a response to injury or disease, maladaptive changes in this pathway may result in an increased pain sensitivity. Clinical observation of the specific malfunctioning of peripheral and central components of this pathway is limited at present, but would permit a better understanding and early selection of interventions for treatment or prevention of chronic pain. Recently, we developed a new method for observing the properties of nociceptive processing utilizing subjective detection of electrocutaneous stimuli in combination with objective neurophysiological brain responses (NDT-EP). In this method, nociceptive afferents are activated by temporally defined current stimuli with varying number of pulses and varying inter pulse intervals. As these different temporal stimulus properties result in different excitation of nociceptive processing mechanisms of the ascending system, subsequent processing of stimulus-response pairs (SRPs) into estimated nociceptive detection thresholds (NDTs) and Evoked brain Potentials (EPs) of multiple stimulus types may provide information about the properties of these mechanisms.

A crucial step in exploring whether the above method could serve as a diagnostic tool is the assessment of the observability of changes in nociceptive function which are relevant for the development or maintenance of chronic pain. This can be achieved by measuring the effect of a well characterized and demonstrated alteration in nociceptive processing mechanisms on the NDTs and EPs. Other research groups have demonstrated that high frequency electrocutaneous stimulation (HFS) of sufficient duration and intensity can be used for prolonged activation of central sensitization mechanisms. These central sensitization effects are observed as a post-HFS secondary hyperalgesia to pin-prick stimuli and considered to play a key role in the development of chronic pain. Other results show that HFS also modulates the EPs obtained by electrocutaneous stimulation on the site of induced secondary hyperalgesia. Recently during a pilot study here at the University of Twente, we have assessed that HFS is technically feasible to implement in our lab.

Doel van het onderzoek

The research is of exploratory nature and therefore does not have hypotheses

Onderzoeksopzet

Only one visit at a single time point is required.

Onderzoeksproduct en/of interventie

High Frequency Stimulation

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(1) A signed, written informed consent; (2) Age between 16 and 40

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

(1) Participant refusal during the study; (2) Language problems; (3) Skin problems at site of stimulation or EEG recording; (4) Diabetes; (5) Implanted stimulation device; (6) Pregnancy; (7) Usage of analgesics within 24 hours before the experiment; (8) Excessive consumption of alcohol or drugs within 24 hours before the experiment; (9) Pain complaints at the time of the experiment; (10) (A medical history of) chronic pain

Onderzoeksopzet

Opzet

| | |
|------------------|-------------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blinding: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

Deelname

| | |
|-------------------------|----------------------|
| Nederland | |
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-07-2020 |
| Aantal proefpersonen: | 20 |
| Type: | Verwachte startdatum |

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 14-09-2021 |
| Soort: | Eerste indiening |

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

| Register | ID |
|----------------|---------------------------------------|
| NTR-new | NL9737 |
| Ander register | CMO Regio Arnhem-Nijmegen : 2020-6265 |

Resultaten