The extent and time-frame of endogenous inhibitory effects after a cold pressor test using a conditioned pain modulation paradigm (ICE study)

Published: 03-09-2014
Last updated: 21-04-2024

In this sub-study we will explore whether the inhibitory effects of conditioned stimuli depent on the subjective experience of pain. Furthermore, we will explore the time-frame of these inhibitory effects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44617

Source
ToetsingOnline

Brief title
NAP study
substudy: ICE study

Condition

- Other condition

Synonym
pain thresholds before and after a cold pressor test

Health condition

pijn systeem, onder andere tijdens slaapdeprivatie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cold pressor test, conditioned pain modulation, pain thresholds

Outcome measures

Primary outcome

Electrical Pain Detection Threshold (EPDT)

EPDT (mA) (baseline)

EPDT (mA) (NRS=0, 6, 10)

EPDT (mA) (t = +1, 5, 10, 15min)

Pressure Pain Detection Threshold (N)

Cold Pressor Test:

CPT (sec) (baseline)

CPT (sec) (NRS=0, 6, 10)

CPM (% EPDT) (NRS=0, 6, 10)

CPM (% EPDT) (t = +1, 5, 10, 15min))

Secondary outcome

not applicable

Study description

Background summary

Several studies suggested the necessity of using painful stimuli as conditioning and as test stimuli to produce inhibitory effects. However, non-painful heat as conditioning stimulus also appeared to be capable of decreasing the ratings of the test stimuli at painful levels (Stefan Lautenbacher, Roscher, & Strian, 2002). Whether the subjective painfulness of the conditioning and the test stimuli forms a prerequisite for the inhibitory action has not yet been investigated in a systematic fashion although inhibitory effects upon non-painful sensations have been observed. The conditioning stimuli in most studies were mainly not assessed for their perceptual qualities. In one study they utilized two conditioning stimuli (heat pain) both very close to pain threshold, one above and one below (S Lautenbacher & Rollman, 1997). Interestingly, these two (heat) stimuli did not differ in their inhibitory effects. In the NAP study we utilize a cold pressor test as conditioning stimulus in accordance with conditioned pain modulation paradigm guideliness described in literature. As far as we know, to date there is no study available that investigated the necessity of using a cold pain tolerance threshold to produce inhibitory effects. Several (above-mentioned) studies suggested less pain stimuli might be capable to reliably activate endogenous inhibitory pathways, and therefore unnecessary to expose study subjects to more painful stimuli. In this sub-study we will explore whether the inhibitory effects of conditioned stimuli depent on the subjective experience of pain. Furthermore, we will explore the time-frame of these inhibitory effects.

Study objective

In this sub-study we will explore whether the inhibitory effects of conditioned stimuli depent on the subjective experience of pain. Furthermore, we will explore the time-frame of these inhibitory effects.

Study design

prospective, observational, mono-center study

Intervention

-2 test sessions

Study burden and risks

Study subjects will undertake a 30-minute experiment at visits at the Intensive

Care Unit Department. Quantitative sensory testing will be performed, including evaluation of endogenous analgesia pathways (conditioned pain modulation) using a cold pressor test (CPT). Risks during participation in this study are negligible. Study session will be performed at the Intensive Care Department. The study will not intervene with daily habits of participating residents. Nocitrack® device used for eQST measurement is approved safe by the Department of Medical Physics of the St. Antonius Hospital [Device number 66294]. ECG electrodes attached to the skin during the use of the Nocitrack® device might give some local skin redness or irritability, however based on former clinical use this is expected to be minimal. Benefit exists in expanding our knowledge about the effects of sleep deprivation on several pain processes.

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

• Healthy male subjects
• Age 25-35 years
• Resident in Anesthesiology, Cardiology, Surgery, Internal Medicine, Orthopedics, Urology, Emergency Medicine.
• Ability to obtain informed consent
• Subject speaks Dutch
• Willingness to comply with study protocol

Exclusion criteria

• Use of analgetics
• History of psychiatric or neurological disease
• Chronic pain disorders
• Diabetes Mellitus
• Systemic illness
• (History of) substance abuse (drugs, alcohol)
• Kidney disease
• Disorders revealed during brief neurological examination
• Dermal lesions at the site of stimulation (i.e. psoriasis, ulcera, infection)
• Pregnancy or breast feeding
• Subject currently has an active implantable device including ICD/pacemaker
• Exams/board reviews or other educational related obligations in the week of study sessions.
• Transmeridian travel within 1 month before the study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2015

Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Quantitative Sensory Testing
Registration:	No

Ethics review

Approved WMO Date:	03-09-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-06-2016
Application type:	Amendment
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	NL49208.100.14