Pain perception of the skin in healthy volunteers and neuropathic pain patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20446

Source
Nationaal Trial Register

Brief title
STIP

Health condition

- Chronic neuropathic pain
- Fibromyalgia
- CRPS
- Diabetic neuropathy
- sarcoidosis

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Initiator sponsors the study

Intervention

Outcome measures

Primary outcome

Response to different kind of pain stimuli

Secondary outcome

N/A

Study description

Background summary

In the current protocol we will perform a variety of sensory tests of the skin and measure the pain response of patients and healthy volunteers. The variety of tests are based on the endogenous pain modulatory mechanism offset analgesia to better understand how healthy persons and patients suffering from chronic pain interpret and modulate pain.

Study objective

The aim of the study is:

(1) observational, i.e., to assess and describe the responses of patients and volunteers to a variety of different stimulation paradigms;

(2) diagnostic, i.e., to assess whether specific tests are possibly diagnostic for specific pain syndromes;

(3) mechanistic, i.e., whether the results of the test may give us valuable information on the site of modulation (central or peripheral).

Study design

All the pain test will be performed on a single occasion on each subject participating in the study.

Intervention

Pain measurement. The Visual Analogue Scale (VAS) will be used to quantify pain intensity in response to a noxious thermal stimulus. The thermal stimulus will be applied on the volar side of the forearm using the thermal probe (a 3 × 3 cm thermode) of the TSA-II NeuroSensory Analyzer (Medoc Ltd, Ramat Yishai, Israel).

We will apply different kind of pain stimuli to the arm:

1) A staircase increase in skin temperature is applied: 2 oC up, 1 oC down until

the eVAS score of 8 cm is reached.

(2) A contant increase in temperature will be applied, from 32 to 51 oC.

(3) A 3 min constant stimulus will be applied.

(4)Offset Analgesia. The temperature will be increased from baseline temperature to the individual's test temperature (eVAS of 5 or 8). The test temperature will be constant for 5 s after which it was raised by 1°C for 5 seconds and next decreased by 1°C to the test temperature and kept constant for 20 seconds.

(5) Four 1 oC up/down tests separated by 10 s performed at an initial eVAS of 8 cm and 5 cm.

(6) An offset analgesia test followed by 1 oC step decreases at 10 s intervals.

(7) Variability testing. In order to get an indication of the effect of the position variability of the thermode on the skin we will measure the pain score to a fixed heat stimulus (a ramp from 32 to 49 oC) on 6 distinct spots on the volar side of the forearm.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients diagnosed with CRPS-1, small-fiber neuropathy, central neuropathic pain or fibromyalgia, according to the guidelines of the IASP or other professional pain societies (eg., Netherlands Society of Anesthesiologists);

2. A pain score of 5 or higher; (iii) age between 18 and 75 years; (iv) being able to give written informed consent.

Volunteer inclusion criteria. Healthy volunteers in the age range 18-75 years of either sex.

Exclusion criteria

1. Unable to give written informed consent;

2. Medical disease such as renal, liver, cardiac, vascular (incl. hypertension) infectious disease;

3. Increased intracranial pressure;

4. Epilepsy;

5. Psychosis;

6. Glaucoma;

7. A history of cerebro-vascular accident < 1 year;

8. Pregnancy;

9. Obesity (BMI > 30).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-06-2013
Application type:	First submission

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
NTR-new	NL3863

Register	ID
NTR-old	NTR4023
Other	: P12.044
ISRCTN	ISRCT wordt niet meer aangevraagd.

Study results

Summary results
N/A