Itch and pain modulation in patients with chronic itch before and after inpatient treatment

Published: 08-03-2011
Last updated: 04-05-2024

Analyses should indicate whether, in line with our hypotheses, CIM and CPM are improved after effective treatment in patients with chronic itch. When the hypotheses are supported, the study provides preliminary evidence for possible treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON34450

Source
ToetsingOnline

Brief title
itch and pain modulation

Condition

- Epidermal and dermal conditions

Synonym
chronic itch, skin diseases

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: Central modulation, itch, Pain, Quantitative sensory testing

Outcome measures

Primary outcome

The dependent variable is the difference in electrically evoked itch before compared to after itch conditioning stimulation (histamine) as a measure of Conditioned Itch Modulation (CIM)..

Secondary outcome

The secundary study parameter is the difference in electrically evoked pain before compared to after pain conditioning stimulation (cold pressor test) as a measure of Conditioned Pain Modulation (CPM)..

Study description

Background summary

Patients suffering from chronic physical symptoms, such as chronic pain and itch, have a lot in common, for example, the mechanisms of peripheral and central sensitization of itch and pain are partly characterized by corresponding patterns.
Conditioned Pain Modulation (CPM) is a pain modulatory mechanism, supposed to be one of the mechanisms that partly explain the susceptibility of chronic pain disorders. CPM is a phenomenon in which one noxious stimulus (the conditioning stimulus) inhibits the pain produced by another. Results showed that CPM is impaired in patients with chronic pain, possibly because of dysregulation of endogenous analgesic systems. We recently showed that itch can be similarly modulated, by a phenomenon called Conditioned Itch Modulation (CIM). Both CPM and CIM has been shown to be impaired in patients with chronic pruritus, which is possibly a consequence of a dysregulation of endogenous itch modulatory systems.
It is known that CPM in chronic pain patients can improve after successful treatment. However, whether CIM and CPM can be improved in patients with chronic itch has not been investigated yet.
Therefore, the aim of this pilot-study is to investigate whether CIM and CPM

can be improved after effective treatment of itch. Furthermore, since there are indications that also CPM is dysregulated in chronic itch, a secondary goal is to investigate whether CPM can improve after effective treatment of itch. We hypothesized that CIM and CPM would improve after effective treatment of chronic itch. When these hypotheses are supported, the results of this study can possibly lead to improved diagnostics and care in patients with chronic itch in the long term.

Study objective

Analyses should indicate whether, in line with our hypotheses, CIM and CPM are improved after effective treatment in patients with chronic itch. When the hypotheses are supported, the study provides preliminary evidence for possible treatment developments for chronic itch to improve diagnostics and care in these patients.

Study design

Subjects and procedures
The study has an observational design without invasive measurements. All measurements will be conducted with approximately 25 patients with chronic itch due to skin conditions (e.g. atopic dermatitis, psoriasis) who are admitted in the clinic. The patients are 18 years or older and have no serious physical or psychiatric co-morbidity that severely interfere with the study protocol. Assessments of itch and pain modulation by using quantitative sensory testing (QST) will take place twice: once within the first three days and once within the last three days during the inpatient treatment.
Power calculations are based on a repeated measures design within one group with an alpha of 0.05. Main effects with an effect size (f) of 0.30 yield a beta of 0.80 and a sample size of 25. The dependent variable in this calculation is the difference in pain induced by electrical stimulation before and after conditioning stimulation.

Self-report measures
Before the first assessment of QST, self report measures which could be related to itch and pain modulation will be assessed e.g. psychological vulnerability factors of neuroticism, hypervigilance and worrying. In addition, validated questionnaires will be used to measure the itch- and health-related quality of life during the past month.

Quantitative sensory testing (QST) of itch and pain modulation

All measures have been previously validated in healthy controls and patients with chronic itch and pain by the research group.
Methodological background: The QST measures are short stimuli of moderate

intensity that are experienced as little burdensome. QST stimuli will be applied before and after treatment to investigate CIM and CPM. QST is a frequently applied method to assess central sensitization in chronic pain using different stimulus modalities and has also been validated for chronic itch. QST is also a frequently used method to demonstrate reduced CPM. In the present study, short electrical test stimuli will be applied before and after the conditioning stimulus for either itch or pain.
Electrical stimulation: After applying cutaneous electrodes, the electrical perception, the unpleasantness and tolerance threshold will be determined in twofold. The maximum stimulation is 15 mA. Short electrical test stimuli are applied to investigate the change in itch and pain resulting from the itch and pain conditioning stimuli, respectively. Patients will first receive threshold measurements and short electrical stimuli of low intensity to familiarize with the stimuli.
CIM: Itch conditioning stimulation is done by application of 0.5% histamine, applied to the subject*s dominant arm by means of iontophoresis with an intensity of 0.4 mA during 2.5 minutes. Before and after the histamine application (itch conditioning stimulation), electrical test stimuli will be used to measure (altered) CIM.
CPM: Pain conditioning stimulation is done by using a cold pressor test. Patients are asked to immerse their dominant hand up to the wrist in water of 4 °C. Patients are instructed to keep their hand in the water as long as possible until it becomes intolerable (with a maximum of 3 minutes). Before and after the cold pressor test (pain conditioning stimulation), electrical test stimuli will be used to measure (altered) CPM.
Dependent measures: Patients are asked to indicate on a VAS scale the intensities of itch and pain evoked by the electrical test stimuli as well as during the itch and pain conditioning stimulation.

Analysis
The data will be analyzed using SPSS. Variables will be checked for normal distribution. To test the main hypothesis, itch and pain scores before and after applying the conditioning stimuli will be analyzed at both measuring points (at the start and at the end of the inpatient treatment), using repeated measures ANOVAs for itch and pain separately.
In addition, Pearson correlation coefficients will be calculated between change scores for itch and pain evoked by the electrical test stimuli, and the following variables: age, gender, educational level, itch and pain scores evoked by the conditioning stimuli (histamine and cold pressor), cold pressor immersion time, individual characteristics, the current skin disease severity and VAS itch and pain on the day of testing.

Study burden and risks

The burden for the patients consists of two QST measurements of 1 hour and completing validated questionnaires one time (30 minutes) (in total 2,5 hours). The validated QST measurements with short stimuli were not considered a burden

by patients in the past (e.g. Laarhoven et al., 2007, 2010).

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postibs 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postibs 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

skin disease that induces itch
minimum age of 18 years
dermatology inpatient treatment

Exclusion criteria

severe physical or psychiatric comorbidity that interferes with the study procotol

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-11-2011
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	08-03-2011
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	NL33770.091.10