Psychoneurobiology of itch symptoms in patients following burn injuries: an explorative study

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The goal of the study is to investigate psychoneurobiological mechanisms of persistent itch in patients following burn injury.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38819

Source
ToetsingOnline

Brief title
Psychoneurobiology of post-burn itch

Condition

- Other condition

Synonym
Patients with itch following burn injury

Health condition

Patienten met brandwondenletsel, minimaal 6 maanden na incident.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: gedeeltelijk door NWO (VIDI),Nederlandse Brandwonden Stichting

Intervention

Keyword: Burn wounds, Itch, Psychoneurobiology, Sensitization

Outcome measures

Primary outcome

This is an explorative study, investigating four different aspects of the psychoneurobiological processing of itch in patients with burn wounds and healthy controls. Since each of the four psychoneurobiological characteristics is individually relevant, the study has four different outcome measures:

1. For the sensory characteristics, visual analogue scale (VAS) scores for itch will be used as primary endpoint for the measurements for itch sensitivity as well as for the central modulation of itch (change in VAS itch).

2. For the neurobiological characteristics, individual alpha-power and peak frequency during resting state EEG as well as in response to itch stimuli (event-related EEG) will be used.

3. For the behavioral characteristics, the reaction time will be determined for the implict tests.

4. For the cognitive-affective characteristics, the total score of validated questionnaires will be used.

Secondary outcome

The secondary endpoint is to explore the autonomic heart rate responses in

response to the psychoneurobiological measurements.

Study description

Background summary

Itch is a common symptom of patients followings burns. The majority of patients experience mild to severe levels of itch even 1-2 years following wound healing after injury. Itch can severely affect the patient's well-being and daily functioning. There is increasing evidence for altered perception and processing of itch e.g., by sensitization processes, in patients with prolonged symptoms of itch. However, these processes have hardly been studied in patients with burn injury. Knowledge on the mechanisms underlying itch may contribute to early identification of patients at risk to develop persistent itch and the early treatment of itch symptoms in burn-injured patients.

Study objective

The goal of the study is to investigate psychoneurobiological mechanisms of persistent itch in patients following burn injury.

Study design

In this experimental study, psychoneurobiological mechanisms of itch in patients with persistent itch following burn injury and healthy subjects will be investigated on four different levels of itch perception and processing, i.e., sensory, neurobiological, behavioral, and cognitive-affective characteristics. To this end, validated and frequently applied methods of quantitative sensory testing (QST), electroencephalography (EEG), implicit tests for measuring automatic behavioral responses to itch, and questionnaires measuring cognitive-affective responses to itch will be used.
This study contributes to our knowledge on the psychoneurobiological mechanisms of itch in burn patients. In line with what is known on the psychoneurobiological processing of itch in patients with persistent itch resulting from skin disease, it is expected that the perception and processing of itch in burn-injured patients might be comparably disturbed.

Study burden and risks

At home, participants first complete a series of validated questionnaires measuring cognitive-affective aspects related to burn wounds, itch or physical symptoms in general (duration ca. 30-45 minutes). Participants will then visit the Radboud University Nijmegen (Medical Centre) once for approximately four hours, including breaks. Non-invasive EEG measurements will be conducted in

resting state, and in response to different quantitative sensory testing (QST) stimuli evoking short-term itch (and/or pain). QST stimuli have frequently been applied in our research group and have been shown to be evoke mild to moderate VAS scores in healthy subjects and patients (e.g., van Laarhoven et al., 2007;2010a, 2010b;2012;2013). QST stimuli also enable the assessment of central itch modulation (van Laarhoven et al., Pain 2010). Simple computer tasks will be applied to measure automatic responses to itch, e.g., the approach-avoidance task (AAT), which have previously been applied within our research group in other patient groups with itch, who experienced the task as not-burdensome. Non-invasive measurements for heart rate will also be conducted. No risks are involved with participation in this study.

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

Age >= 18 years.
Itch symptoms up to at least 6 months after burn injury (for patients with burn wounds only)

Exclusion criteria

1. Severe physical or psychological morbidity that would adversely affect participation (e.g., heart- or lung disease or DSM-IV diagnoses).
2. Use of pacemaker.
3. Pregnancy.
4. Burn wounds affecting the head (due to EEG measurements).
5. Chronic pain or itch symptoms with medical cause other than burn wounds.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	21-11-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-12-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-04-2014
Application type:	Amendment
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	NL43955.091.13