Pathophysiology of cold intolerance in different patient groups

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Main objectiveTo describe the experienced pain sensations of temperature and to describe the different temperature sensitivity thresholds using Quantitative Sensory Test (QST) in the different patient groups.secondairy objectiveAs a measure of the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Thyroid gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35399

Source
ToetsingOnline

Brief title
Pathofysiology of cold intolerance in different patient groups

Condition

- Thyroid gland disorders
- Bone and joint injuries
- Neuromuscular disorders

Synonym
Cold Sensitivity, pain during cold

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cold intolerance, Different patient groups, Quantitative sensory testing, Thermoregulation

Outcome measures

Primary outcome

The questionnaire has a minimum score of 0 and a maximum of 100 points. The

temperature-sensitive analysis, will compare the temperature in Celsius

degrees. The re-warming is given by Q as number of added energy in joules and

compared with de patient groups as well as the control group.

Secondary outcome

N.V.T

Study description

Background summary

The pathophysiology of cold intolerance is still unknown. Cold intolerance is a disabilitating disease with a relatively high incidence for many different patient groups (fracture patients 38% and nerve injury patients between 56 and 70%). A good diagnosis and definition for cold intolerance is missing.

Study objective

Main objective
To describe the experienced pain sensations of temperature and to describe the different temperature sensitivity thresholds using Quantitative Sensory Test (QST) in the different patient groups.
secondairy objective
As a measure of the quality of thermoregulation the re-warming pattern after cooling the hands of the patient groups will be assessed. In addition the relationships between re-warming patterns, sensory recovery and CI will be assessed.

Study design

Measurements will initially start in the control group, followed by the cold intolerant patients. The presence of cold intolerance is based on the Cold Intolerance Symptom Severity questionnaire (CISS), developed by McCabe. Patients will be informed by the doctor and receive the PIF (patient information form). The patient will be required to reply with an answering card indicating that they are willing to participate. When the answering card is received an appointment for the measurements will be made and the patient will be included in the study.
The patient will fill out the CISS and the RCIQ. General patient information will be obtained such as gender, age, length, weight, smoking, date of trauma, cause of trauma, medication, occupation, change of occupation, ability to work, etc.
A qualified nurse at the pain treatment centre will measure the blood pressure. Temperature of both hands will be assessed. Sensibility testing will be performed with the Semmes and Weinstein monofilaments before applying the temperature sensibility testing.
Sensitivity and pain temperature thresholds of the hands will be analysed with a Temperature Sensory Analyser.
The hands of the patients will be cooled in water of 15 ºC and will stay in the water for 90 seconds before quickly drying the hands by the researcher. The hands will be placed underneath the thermographic camera. The re-warming of the patient takes approximately 15 minutes.

Study burden and risks

The burden of the patient is a 1-time visit to our clinic. As to our knowledge there are no risks for 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

minimum age >18, that are being treated in our hospital. All patients will have the pathological cold intolerance according to Ruijs et al., that is, a CISS score higher than 30.

Exclusion criteria

* Diseases, that influence the vascular system (such as Diabetes and Raynaud),
* Cardiac diseases and use of cardiac pharmacological supplements (α1,2-blockers and β1-blockers).
* Foreign material in the hand of the patient such as metal operation plates.
* Carpal tunnel syndrome
* Previous application of steroid injections if used in the past five years
* History of musculoskeletal medical conditions (e.g. Rheumatoid arthritis, Fibromyalgia)
* use of antihypertensive drugs

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL29382.078.09