

# Incidence and severity of cold intolerance in patients with handfractures and patterns of rewarming of the hands after cooling

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This study will give an insight in the incidence of cold intolerance of patients with a fracture of the hand. This study will also show if there is a relation between the rewarmingpattern and the cold intolerance of patients with a hand fracture.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Bone and joint injuries
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON31998

### Source

ToetsingOnline

### Brief title

Cold Intolerance after hand fractures

### Condition

- Bone and joint injuries

### Synonym

cold intolerance, 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, Hand fracture, Incidence, Rewarming pattern

## Outcome measures

### Primary outcome

The primary study parameter is the CISS-score. The questionnaire consists of 6 questions, with a total score of 100. Ruijs et al. defined that the cut-off point for the diagnosis cold intolerance is 30.

The second study parameter is the Q-value calculated out of the rewarmingpattern of the patient.

### Secondary outcome

N.V.T.

## Study description

### Background summary

To our knowledge, little is known about the incidence of cold intolerance of patients with hand fractures. The incidence of cold intolerance of patients with nerve damage has been described by Ruijs et al. Depending on the severity of the nerve damage the incidence is 56% -70%. Since these incidence are that high, a new experiment is necessary to study if cold intolerance is also seen in patients with hand fractures.

Secondly Ruijs et al described the relation between cold intolerance and the rewarmingpattern after cooling of the hand. Compared to hands without any nerve damage the rewarmingpattern of patients with nerve damage was different.

### Study objective

This study will give an insight in the incidence of cold intolerance of patients with a fracture of the hand. This study will also show if there is a relation between the rewarmingpattern and the cold intolerance of patients with

a hand fracture.

## **Study design**

### **Part I**

The patients group will receive a patient information form. This form also includes a form for informed consent. If the patient has given informed consent, the patient will receive the CISS-questionnaire.

### **Part II**

The research group will select a new group of patients using the CISS-score as criterium. This new group will be informed via a new patients information form about the measuring of their rewarming pattern. After giving a new informed consent, the patient will be contacted by phone to make an appointment for the measuring.

## **Intervention**

N.V.T.

## **Study burden and risks**

The burden of the patient is a 1-time visit to our clinic. In our clinic the patients hands will be cooled for 90 seconds in a bath with a water temperature of 13° Celsius.

As to our knowledge there are no risks for this study. However, for extra safety all patients will use laser safety glasses for protection of the laser light during the laser-doppler measuring.

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Handfracture

### Exclusion criteria

Nerve damage

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting

Start date (anticipated):	18-07-2008
Enrollment:	200
Type:	Actual

## Ethics review

Approved WMO	
Date:	09-06-2008
Application type:	First submission
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	NL21765.078.08