

# Cortical processing of pain: effect of a conditioning stimulus and radicular pain

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Reserach to the observation of neurophysiologic pain mechanisms and the differences between healthy subjects and pain patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Spinal cord and nerve root disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31230

### Source

ToetsingOnline

### Brief title

Cortical processing of pain

## Condition

- Spinal cord and nerve root disorders

### Synonym

Radicular pain

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cold pressor test, Evoked potential, Pain, Radicular pain

## Outcome measures

### Primary outcome

Reported pain experience (0-100)

Amplitudes of the EP components measured at CZ-A1A2 (P90, N150, P200 and P300)

Amplitudes of the EP components measured at C4-FZ and C3-FZ (P50 and N90)

### Secondary outcome

Cortical areas

data from diagnosis file of radicular pain patients

area of compression or irritation radix

nature of pain complaints

duration of pain complaints

medication

applied diagnosis techniques

treatment patients

## Study description

### Background summary

Chronic pain is an increasing problem for both healthcare and the social security system as for medical science. Still a lot is unknown about the neurophysiological pain mechanisms underlying chronification of pain.

### Study objective

Research to the observation of neurophysiologic pain mechanisms and the differences between healthy subjects and pain patients.

### Study design

The stimulation location of the electrical stimulus (left forearm or left middle fingertip) is the only difference between both experiments. In an experiment the electrical stimulus will be modulated by two different methods; by modulation the amplitude of a single pulse or modulation of the number of pulses in a pulse train with fixed amplitude. In combination with the electrical stimulus the subject will put his right hand up to the wrist in ice water or water with the temperature of 32°C (warm nor cold). Besides reported pain experience, the brain activity after the electrical stimulus will be measured by electroencephalography (EEG). A part of the subjects will be measured twice.

### **Study burden and risks**

The used methods are non invasive. The maximal duration of an experiment is 2.5 hour. The actual duration of the measurement will be 1 hour. During the rest of the time the EEG electrodes and stimulation electrode will be fixed (45 minutes) and there will be breaks between the measurements (45 minutes). There are no considerable physical or mental risks joined with this research.

## **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

For both healthy and radicular pain patients

Right handed

age 18-65

Radicular pain patients

radicular pain syndrom diagnosed by the neurologist or clinical neurophysiologist

### Exclusion criteria

Both healthy and radicular pain patients:

Psychotropic medication

healthy subjects:

pain complaints during the experiments

pain complaints for more than 1 week during previous 3 months

psychotropic medication

Radicular pain patients

other pain complaints; Radicular pain patients:

psychotropic medication

other pain complaints

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	120
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Twente (Enschede)

## 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	NL17719.044.07