

# Emotional modulation of pain perception in experimental and clinical neuropathy: an fMRI study.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Diabetic complications
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31472

### Source

ToetsingOnline

### Brief title

Emotional Modulation of Pain Perception

### Condition

- Diabetic complications
- Ancillary infectious topics
- Peripheral neuropathies

### Synonym

allodynia, chronic nerve pain, hyperalgesia, peripheral neuropathy

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Public Dutch TIP Foundation

## Intervention

**Keyword:** emotional context, functional magnetic resonance imaging, neuropathic pain models, neuropathy

## Outcome measures

### Primary outcome

Cerebral activation patterns.

### Secondary outcome

Behavioral questionnaire results, subjective pain ratings

## Study description

### Background summary

Neuroimaging studies of neuropathic pain qualities referred to as allodynia and hyperalgesia suggest that (a) no specific substrates in addition to known structures in the pain neuromatrix are engaged, but that (b) these specific pain qualities are represented in the affective circuit of the pain matrix.

### Study objective

It is therefore planned to study pain perception in peripheral neuropathy in the context of positive and negative emotional stimulation. Although there is a recent plea for the study of emotional modulation of pain, only one study has as yet done so for visceral enteroception. The present study aims at contrasting sensory and affective circuits of the pain neuromatrix in neuropathy to controls according to emotional context type. These results will be linked to self-report and genetic data.

### Study design

Clinical group comparison between neuropathy and normal control subjects. Event-related fMRI design with 1 neutral pain level, 3 individually established pain levels, and one visual emotional (positive or negative) stimulus class. Four experimental runs of each 20 minutes duration will enable 2 x 2 factorial analysis: Limb-right, limb-left, emotion-positive, emotion-negative. Per experimental run of 20 minutes, a total of 100 heat/cold or visual emotional

stimuli will be presented; subjects rate subjective stimulus intensity.

### **Study burden and risks**

Risks are minimal. Burden is to tolerate and rate pain application to a limb and stay in an MRI scanner. The subjects will receive monetary compensation; they contribute to better understanding of brain circuitry involved in abnormal pain perception in neuropathy.

## **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**

right handed patients suffering from neuropathy

## Exclusion criteria

any metallic implants, history of substance use, psychiatric or neurological problems

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2008
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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

CCMO

### ID

NL21056.042.07