

# Pregabalin in patients with central neuropathic pain: a randomised, double-blind, placebo-controlled trial of a flexible-dose regimen

<b>Submission date</b> 22/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/07/2009	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr M R Kruis

**Contact details**  
Academic Medical Center (AMC)  
Pijncentrum  
P.O. Box 22660  
Amsterdam  
Netherlands  
1100 DD

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NTR852; 1

# Study information

## Scientific Title

## Study objectives

We tested, in a randomised, double-blind, placebo-controlled trial, the effects of pregabalin on pain relief, tolerability, health status, and quality of life in patients with central neuropathic pain.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee

## Study design

Randomised, triple blind, placebo controlled, parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Central neuropathic pain

## Interventions

Pregabalin versus placebo.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Pregabalin

## Primary outcome measure

The primary efficacy parameter is a pain intensity score recorded by patients (at baseline, and four weeks following treatment), using a Visual Analog Scale (VAS).

## **Secondary outcome measures**

Health status and Quality of Life (QOL) questionnaires (secondary outcomes) were completed before start of treatment and four weeks following start of treatment.

Health status and QOL measurements included the Pain Disability Index (PDI), the EuroQoL questionnaire (EQ-5D), and the Medical Outcomes Short-Form Health Survey questionnaire 36 (SF 36).

## **Overall study start date**

01/01/2006

## **Completion date**

30/12/2006

# **Eligibility**

## **Key inclusion criteria**

1. Age 18 years or older
2. Written informed consent
3. Patients suffering from severe neuropathic pain caused by lesion or dysfunction in the central nervous system. Neuropathic pain was described by at least one of the following:
  - a. burning pain
  - b. paroxysmal episodes of shooting pain
  - c. pain on light touch

Additionally, patients had to score above 12 on the Leeds Assessment of Neuropathic Symptoms and Signs questionnaire (LANSS)

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Not Specified

## **Target number of participants**

40

## **Key exclusion criteria**

1. Pregnant
2. Had a history of intolerance, hypersensitivity, or known allergy to pregabalin
3. Had a known history of significant hepatic, renal, or psychiatric disorder
4. Had a history of galactose-intolerance, lactase deficiency, or glucose-galactose malabsorption syndrome
5. Subjects with a calculated creatinine clearance rate below 60 mL/m (estimated from serum creatinine using Cockcroft-Gault equation) were specifically excluded

6. No new analgesic therapies were to be initiated at any time during the trial
7. Patients who had been exposed previously to gabapentin, regardless of dose and treatment duration, were permitted to enter the study. However, treatment with gabapentin was to be discontinued at least three days before receiving study medication

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

30/12/2006

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Academic Medical Center (AMC)**

Amsterdam

Netherlands

1100 DD

## **Sponsor information**

**Organisation**

Academic Medical Center (AMC) (Netherlands)

**Sponsor details**

Department of Anesthesiology

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.amc.uva.nl/>

**ROR**

<https://ror.org/03t4gr691>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Academic Medical Center (AMC) (The Netherlands)

## Alternative Name(s)

Academic Medical Center, AMC

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

Netherlands

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2008		Yes	No