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

Submission date 22/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/01/2007	**Overall study status** Completed	
Last Edited 06/07/2009	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 Cockroft-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
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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?
Results article	results	01/05/2008		Yes	No