Vermindert duloxetine de neuropathische pijn bij patiënten met het centrale pijnsyndroom?
Een dubbelblind gerandomiseerd onderzoek.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23743

Source
NTR

Brief title
DOL

Health condition

1. Central pain;

2. duloxetine;

3. quality of life;

4. spinal cord lesion.

(NLD: centrale pijn, kwaliteit van leven, ruggenmergtrauma).

Sponsors and support

Primary sponsor: Academic Medical Center- Department of anesthesiology - Pain relief Unit.

Meibergdreef 9, 1105 AZ, Amsterdam
Source(s) of monetary or material Support: Academic Medical Center

Intervention

Outcome measures

Primary outcome

The primary efficacy parameter is a pain intensity score recorded by patients (at baseline, and 8 weeks following treatment), using a visual analog scale (VAS).

Secondary outcome

Health status and quality of life (QOL) questionnaires (secondary outcomes) are to be completed before start of treatment and 8 weeks following start of treatment. Health status and QOL measurements include the Pain Disability Index (PDI), the EQ-5D, and the Medical Outcomes Short-form Health Survey questionnaire 36 (SF36).

Study description

Background summary

Central neuropathic pain (pain associated with lesions of the central nervous system) has been estimated to occur in up to 8% of patients after a stroke, and about 10% to 30% of patients with spinal cord injury are affected during the course of their illness.

(1) The mechanisms underlying central neuropathic pain are not completely understood. A dominating feature of central pain, however, is an abnormal spinothalamic function with altered sensitivity to temperature and pinprick.

(2) Disruption of the spinothalamic pathways may contribute to neuronal hyperexcitability, loss of descending inhibitory control mechanisms in the spinal cord, and alterations in the processing of incoming noxious and non-noxious stimuli resulting in an abnormal pain perception (1; 3). In addition, loss of balance between noxious and non-noxious sensory inputs gives rise to neuronal reorganization in the thalamus contributing to the onward flow of nociceptive information to the postcentral gyrus of the cortex (4). Despite recent advances in identification of peripheral and central sensitization mechanisms related to central nervous system injury, the effective treatment of patients suffering from central pain remains a clinical challenge. Nevertheless the numerous treatment options available (including opioids, anticonvulsants, antidepressant, baclofen, á-adrenergic agonists, and ketamine), some of these patients still experience severe neuropathic pain. In addition, the use of these agents is often limited by significant side effects. Recently, duloxetine was reported to possess

antihyperalgesic and antiallodynic properties in a wide range of animal models, and to be effective in randomized clinical trials of nonmalignant chronic neuropathic pain (including fibromyalgia and diabetic peripheral neuropathy). Although recent trials confirm the effectiveness of duloxetine in peripheral neuropathic pain, the role of pregabalin in the treatment of central neuropathic pain remains unknown. Given the absence of other effective pharmacological treatments for central pain, any medication providing some benefits in terms of symptom amelioration and quality of life improvement in patients with neuropathic pain have to be evaluated.

Study objective

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

Study design

Each week, pain intensity score is used as a guide to evaluate treatment.

Intervention

Duloxetine versus placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 years or older;

2. Written informed consent;

3. Patients suffering from severe neuropathic pain (VAS > 6) caused by lesion or dysfunction in the central nervous system. Neuropathic pain was described by at least one of the following: burning pain, paroxysmal episodes of shooting pain, or pain on light touch. Additionally, patients had to score above 12 on the Leeds Assessment of Neuropathic Symptoms and Signs questionnaire.

Exclusion criteria

1. Pregnant;

2. Had a history of intolerance, hypersensitivity, or known allergy to duloxetine;

3. Had a known history of significant hepatic, renal, or psychiatric disorder;

4. No new analgesic therapies are to be initiated or changed less than 6 weeks before commencing the trial or at any time during the trial;

5. Patients who are on antidepressant treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	48
Type:	Actual

Ethics review

Positive opinion

Date:	10-12-2007
Application type:	First submission

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
NTR-new	NL1125
NTR-old	NTR1160
Other	MEC : 06/254
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A