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

Gepubliceerd: 10-12-2007 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23743

Bron
Nationaal Trial Register

Verkorte titel
DOL

Aandoening

1. Central pain;

2. duloxetine;

3. quality of life;

4. spinal cord lesion.

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

Ondersteuning

Primaire sponsor: Academic Medical Center- Department of anesthesiology - Pain relief Unit. Meibergdreef 9, 1105 AZ, Amsterdam
Overige ondersteuning: Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Duloxetine versus placebo.

Contactpersonen

Publiek

Academic Medical Center (AMC), Pijncentrum,
P.O. Box 22660
M.R. Kruis
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662292

Wetenschappelijk

Academic Medical Center (AMC), Pijncentrum,
P.O. Box 22660
M.R. Kruis
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662292

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	48
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-12-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1125
NTR-old	NTR1160
Ander register	MEC : 06/254
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A