Effects of Continuous Intravenous Magnesium on Features of Central Sensitisation in CRPS1 patients.

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Magnesium Sulphate reduces pain for more than 50% on the Box scale when compared to the baseline, and for more than 2 points to the placebo group.

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

Samenvatting

ID

NL-OMON28022

Bron
NTR

Verkorte titel
N/A

Aandoening

CRPS1

Ondersteuning

Primaire sponsor: VU University Medical center, Department of Anesthesiology.
Overige ondersteuning: BSIK03016

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain will be measured in a pain diary at baseline, 1, 3, 6 and 12 weeks after treatment. In this

diary patients will record their pain rate on a 11 point Box scale 3 times daily for a period of one week before each measurement point.

Toelichting onderzoek

Achtergrond van het onderzoek

There is increasing evidence suggesting that the inflammatory response in Complex Regional Pain Syndrome type 1 (CRPS1) may result from a perturbed function of C and Adelta-fibres releasing neuropeptides in response to tissue damage. This process may initiate chemical and physiological changes at the spinal chord level that are associated with increased excitability of neurons, such that spontaneous pain, allodynia and/or hyperalgesia occur. This process of central sensitisation is considered a leading factor in the development of chronic pain. To counter this neurogenic wind-up phenomenon, and counter the vicious circle of sensitisation and further release of neuropeptides, NMDA antagonists are being used. Evidence in acute as well as chronic pain treatment suggests that Magnesium prevents the activation of the NMDA mechanism responsible for the generation of neuropathic pain. This randomised, double blind placebo-controlled study will be performed to evaluate the involvement of NMDA receptor activation in the pathophysiology of CRPS1. Furthermore, the effect of Magnesium on pain, functional status, and quality of life in CRPS1 patients will be compared between Magnesium and Sodium chloride (NaCl) infusion.

Doel van het onderzoek

Magnesium Sulphate reduces pain for more than 50% on the Box scale when compared to the baseline, and for more than 2 points to the placebo group.

Onderzoeksproduct en/of interventie

Intravenous Magnesium or placebo.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnostic criteria for CRPS1 according to the IASP (1):
a. Presence of an initiating noxious event or cause for immobilisation;
b. Continuing pain, allodynia or hyperalgesia, with which the pain is disproportioned to any inciting event and is not limited to the area of an individual peripheral nerve;
c. Evidence at any time of oedema. Skin blood flow abnormality, or abnormal sudomotor activity in the painful area since the inciting event;
d. Conditions which could otherwise account for the level of pain and dysfunction should be excluded;
Note: criteria b-d have to be met.
2. A VAS-spontaneous pain score of 5 cm or higher;
3. Patients should be between 18 -70 years old;
4. CRPS1 in one extremity;
5. First time experience of patient with CRPS1;
6. Other medication has to be stopped for more then one week before the trial starts;
7. Patients should give written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not being able to give informed consent;
2. Another (2nd) chronic pain syndrome, interfering with pain ratings;
3. Another syndrome interfering with functional tests;
4. CRPS1 in both hands or feet;
5. Patient has experienced CRPS1 before;
6. Known kidney and/or severe liver disease;

7. Known nerve damage in the affected area;
8. Active infection;
9. Mental retardation;
10..Psychiatric abnormality ;
11. Malignant disease;
12. Patients with heart failure;
13. Patients with pacemakers or implanted defibrillators;
14. Patients with pulmonary congestion;
15. Pregnancy.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2006
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-11-2006
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	NL797
NTR-old	NTR810
Ander register	: N/A
ISRCTN	ISRCTN66289967

Resultaten

Samenvatting resultaten
N/A