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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28022

Source
NTR

Brief title
N/A

Health condition

CRPS1

Sponsors and support

Primary sponsor: VU University Medical center, Department of Anesthesiology.
Source(s) of monetary or material Support: BSIK03016

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Sensory complaints:
McGill pain questionnaire will be used to obtain information about the type of pain experienced by patients. Semmes Weinstein Monofilaments will be used to objectively measure sensitivity of the skin (e.g. hypesthesia, hyperesthesia and allodynia).
Impairments:
Patients functional status will be assessed with the Impairment Level Sumscore, in which pain (measured by Box scale and McGill pain questionnaire), temperature (measured with infrared thermometer), volume (measured with water displacement volumeter) and active range of motion (measured with goniometers) will be converted into a compound sumscore.
Functional disability: The Radboud Skills Questionnaire, the Walking Stairs Questionnaire and Questionnaire Rising and Sitting Down will be used to assess diasability in patients with respectively upper and lower CRPS1.
Quality of life: The Short Form-36 and EuroQol will be used to measure quality of life.

Study description

Background summary

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.

Study objective

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.

Intervention

Intravenous Magnesium or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2006
Enrollment:	72
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-11-2006
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	NL797
NTR-old	NTR810
Other	: N/A
ISRCTN	ISRCTN66289967

Study results

Summary results
N/A