Double-blind randomised placebo-controlled cross-over study to investigate the effectiveness of intramuscular magnesium on pain and dystonia in Complex Regional Pain Syndrome type 1.

No registrations found.

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

Summary

ID

NL-OMON22797

Source
NTR

Brief title
the IMCORE study

Health condition

Dystonia in complex regional pain syndrome type 1.

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: TREND-consortium (acronym for trauma related neuronal disorder)

Intervention

Outcome measures

Primary outcome

Primary outcome is severity of dystonia using the Burke-Fahn-Marsden scale.

Secondary outcome

Secondary outcomes are:

1. Efficacy as evaluated by pain and dystonia severity using NRS, McGill Pain Questionnaire, a device measuring the passive joint range of motion and muscle resistance to passive movement, patient's preference questionnaire (PPQ), and global impression of improvement after each treatment (global impression scale);

2. Safety of the procedure as evaluated by the occurrence of adverse events.

Study description

Background summary

A large proportion of chronic patients with complex regional pain syndrome type 1 (CRPS I) suffer from both neuropathic pain and dystonia. Findings from neurophysiological and intrathecal baclofen (ITB) studies highlight an impaired inhibitory neurotransmission. Since magnesium plays an important inhibitory role in motor regulation, magnesium administration may offer new options for the treatment of movement disorders in patients with CRPS I. Primary aim of the study is to evaluate the efficacy and safety of intramuscular magnesium (IMMG) in CRPS I in a double-blind randomised placebo-controlled cross-over manner.

Study objective

Administration of magnesiumsulphate has the potential to elicit muscle relaxation. We hypothesize administration of intramuscular magnesiumsulphate can reduce CRPS-related dystonia.

Study design

One week before first injection until 7 weeks after first injection:

1. Self-assessment every day;

2. Other assessments once every week.

Intervention

Intramuscular magnesiumsulphate:

1. Week 1: 500 mg twice a day;

2. Week 2: 750 mg twice a day;

3. Week 3: 1000 mg twice a day.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients must fulfill the diagnostic criteria of the consensus report of CRPS I:

A. Continuing pain, allodynia or hyperalgesia, in which the pain is disproportionate to any inciting event, and;

B. Evidence at some time of edema, changes in skin blood flow or abnormal sudomotor activity in the region of the pain, and;

C. No condition that would otherwise account for the degree of pain and dysfunction.

2. Patients must suffer from clinically significant tonic or intermittent dystonia in one or more extremities;

3. Patients must have symptoms for at least 1 year.

Exclusion criteria

1. Patients are excluded if they can obtain satisfactory relief of symptoms with conventional treatments;

2. Patients with a history of alcohol or drugs abuse within the past year;

3. Patients with clinically significant psychiatric illness;

4. Pregnant, nursing women and females of childbearing potential not using effective contraception;

5. Patients who are unlikely to comply with study requirements or have a history of poor compliance to medical regimens or study requirements;

6. Patients with an insufficient command and understanding of the Dutch language;

7. Patients involved in legal proceedings (claiming compensation for their CRPS I);

8. Patients with impaired coagulation;

9. Patients with impaired renal function (i.e. serum creatinine below 10 or exceeding 80 µmol/l);

10. Patients with hypermagnesaemia (i.e. total serum Mg exceeding 1.10 mmol/l);

11. Patients requiring the use of diuretics.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-06-2009
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	NL1763

Register ID

NTR-old	NTR1873
Other	NL26827.058.09 (Centrale Commissie Mensgebonden Onderzoek) : P09.021 (METC AMC)
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A