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

Published: 19-02-2009
Last updated: 18-07-2024

Primary aim of the study is to evaluate the efficacy and safety of intramuscular magnesiumsulphate in CRPS I patients during 3 weeks dose escalation study.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON33281

Source
ToetsingOnline

Brief title
Intramuscular Magnesium for COmplex REgional Pain Syndrome (IMCORE)

Condition

- Movement disorders (incl parkinsonism)

Synonym
dystonia of enlarged muscle tone

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ministerie van economische zaken

Intervention

Keyword: CRPS I, intramuscular, magnesium

Outcome measures

Primary outcome

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

Secondary outcome

1. Severity of pain and dystonia using a NRS.

2. Severity of pain using the McGill Pain Questionnaire.

3. Assessment of the severity of dystonia using a device measuring the passive

joint range of motion, and muscle resistance to passive movement.

4. Patient Preference Questionnaire.

5. The global impression scale.

6. Safety of the procedure as evaluated by the occurence of adverse events.

Study description

Background summary

Many patients with dystonia in CRPS I show insufficient or no benefit on oral medication, physiotherapy, splints or other treatments. Administration of intrathecal baclofen is an invasive treatment since a pumpimplantation is required combined with the risk of technical complications to the pumpsysteem. The administration of magnesiumsulphate proved to have a muscle relaxant effect in many areas and intramuscular administration is possible, which supports adequate systemic distribution and treatment over a longer period of time on a daily basis. Furthermore patiënts are able to autoinject the studymedication in

their own environment.

Study objective

Primary aim of the study is to evaluate the efficacy and safety of intramuscular magnesiumsulphate in CRPS I patients during 3 weeks dose escalation study.

Study design

Forty patients suffering from CRPS type 1 and dystonia will receive intramuscular magnesiumsulphate (3 weeks) and placebo (3 weeks) in a dubbelblind crossover manner. Every week for a period of 3 weeks the dose of study medication will be raised following a predefined dose escalation scheme. After the first 3 weeks no study medication will be administered for one week to create a washout period. The next 3 weeks study medication is resumed following the dose escalation scheme identical to the first period.

Intervention

Intramuscular treatment with magnesiumsulphate or placebo (NaCl 0,9%). Administration will start with a dose of 500 mg, two times a day, and raised to a maximum of 750 mg, three times a day or 1000 mg, twice a day.

Study burden and risks

1. risk of pain at the site of injection
2. a slight risk of exacerbation of symptoms of CRPS as the injection resembles a minor traumatic event

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients must fulfill the diagnostic criteria of the IASP 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
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Magnesium Sulphate
Generic name:	Magnesium Sulphate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-02-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	22-06-2009
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
EudraCT	EUCTR2009-010087-42-NL
CCMO	NL26827.058.09