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

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A large proportion of chronic patients with complex regional pain syndrome type 1 suffer from both neuropathic pain and dystonia. Findings from neurophysiological and intrathecal baclofen studies highlight an impaired inhibitory neurotransmission....

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

Samenvatting

ID

NL-OMON27048

Bron
Nationaal Trial Register

Verkorte titel
The ITG study (ITG is an abbreviation for intrathecal glycine)

Aandoening

Complex Regional Pain Syndrome type 1 (CRPS I)

Ondersteuning

Primaire sponsor: Dept. of Neurology, Leiden University Medical Centre
Overige ondersteuning: Ministry of Economic Affairs

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is the safety of ITG.
Safety evaluations include history taking, physical examination and neurological examination, blood and cerebrospinal fluid assessments and 12-lead electrocardiography (ECG).

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

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 studies highlight an impaired inhibitory neurotransmission.
Since glycinergic neurotransmission plays an important inhibitory role in afferent and motor processing, glycine administration may offer new options for the treatment of both pain and movement disorders in patients with CRPS I.

Aim of the study:

- Primary aim of the study is to evaluate the safety of intrathecal glycine (ITG) in CRPS I patients.

- Secondary aim is to study the effectiveness of ITG treatment during 4 weeks (in an increasing dose schedule).

SUBJECTS:

Subjects will be male or female out-patients, at least 18 years of age, with a clinical diagnosis of CRPS I related dystonia who are referred to the movement disorders out-patients' clinic of the department of Neurology at the Leiden University Medical Centre (LUMC) for intrathecal baclofen treatment.

Methods:

The ITG study is a double-blind randomised placebo-controlled cross-over study.
For future intrathecal baclofen treatment, in all patients a programmable pump for continuous intrathecal administration is implanted.
Study treatment is started at a dosage of 8/21 mL/24 hours and will be weekly increased with 8/21 mL/24 hours.
In case of adverse events, dose will be halved (and if needed repeated) or stopped, depending on the opinion of the investigators.
Safety and efficacy are assessed by means of standardized evaluation.
Patients are assessed 2 weeks before pump implantation and during both treatments at day 1, day 2, day 4, day 8, day 15, day 22 and day 29.

Doel van het onderzoek

A large proportion of chronic patients with complex regional pain syndrome type 1 suffer from both neuropathic pain and dystonia. Findings from neurophysiological and intrathecal baclofen studies highlight an impaired inhibitory neurotransmission. Since glycinergic neurotransmission plays an important inhibitory role in afferent and motor processing, glycine administration may offer new options for the treatment of both pain and movement disorders in patients with CRPS I.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

For future intrathecal baclofen treatment, in all patients a programmable pump for continuous intrathecal administration (SynchroMed® pump, Medtronic, Minneapolis MN, USA, 40 mL reservoir) and a lumbar reservoir for cerebrospinal fluid sampling will be implanted.
Each subject receives two treatments:
1. 2.1% glycine solution during 4 weeks and
2. natrium chloride 0.9% during 4 weeks (placebo).
Study treatment is started at a dosage of 8/21 mL/24 hours (during treatment with glycine 2.1% this corresponds to 8 mg/24 hours) and will be weekly increased with 8/21 mL/24 hours.
There is a tapering and wash-out period after each treatment: tapering in 1 week (3 equal dose decreases with an interval of 48 hours, e.g. monday 22, wednesday 12 and friday 0 mg/24 hours) and wash-out in 1 week.
Treatment is started on mondays.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients must fulfil 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;

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

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	21-11-2005
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-11-2005
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	NL458
NTR-old	NTR499
Ander register	: P05.108
ISRCTN	ISRCTN75413193

Resultaten

Samenvatting resultaten
N/A