The influence of different flow rates of intrathecal baclofen infusion on dystonia and pain in Complex Regional Pain Syndrome type 1

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The infusion of intrathecal baclofen using higher flow rates results in more extensive intrathecal distribution, hence benefits pharmacodynamic properties of baclofen

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

Samenvatting

ID

NL-OMON20461

Bron
NTR

Verkorte titel
The ITB Flow Rate Study

Aandoening

Complex Regional Pain Syndrome type 1

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Department of Neurology
Overige ondersteuning: Leiden University Medical Center (LUMC), Department of Neurology, Medtronic Europe S.A., Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severity of pain and dystonia using a NRS.

Toelichting onderzoek

Achtergrond van het onderzoek

A double-blind randomized two-period cross-over study will be used to analyse the efficacy of a 4-times higher flow rate of ITB on dystonia and pain in CRPS I.

Primary outcomes are severity of pain and dystonia using a NRS.

Secondary outcomes are:

1. Efficacy as evaluated by dystonia severity (Burke-Fahn-Marsden scale), patient¡¯s preference (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.

To study the difference in outcome between both flow rates, a paired samples t-test (or Wilcoxon Signed Rank Test in case of non-normal distribution) will be used. Differences are considered significant if the p values are ¡Ü 0.05. The frequency and severity of adverse events will be compared between both regimes.

Doel van het onderzoek

The infusion of intrathecal baclofen using higher flow rates results in more extensive intrathecal distribution, hence benefits pharmacodynamic properties of baclofen

Onderzoeksopzet

1. Every day from last week before until 5 weeks after first switch of ITB concentration (NRS-score)

2. Day 1, 14, 21 and 35 after first switch of ITB concentration (history, examination, Burke-Fahn-Marsden score, Global Impression Score, Patient Preference Questionnaire)

Onderzoeksproduct en/of interventie

1. Before the start of the study all patients have received continuous ITB with a concentration of 3000 µg/ml.
The study starts with replacing the current substitution of 3000 µg/ml baclofen by randomly allocated 3000 µg/ml or 750 µg/ml concentrations of ITB. To maintain a fixed daily dose of ITB, flow rates will be adjusted accordingly to the administered concentration (3000 µg/ml - no change; 750 µg/ml ¨C 4-fold increase).

2. During a 2 week period, the first allocated flow rate will be used.
The following week, baclofen will be administered using the baseline flowrate in an unblinded manner (patient & rater) to minimize potential consequences of any carry-over effect.

Subsequently, the following 2 week period the second allocated flow rate will be used after which all patients will continue on open ITB using the baseline flow rate.

3. Changing the different flow rates requires a special switch procedure, which will be carried out by a physician not involved in the assessments of the patients.

4. If a baclofen-related side-effect occurs, the flow rate will be reduced to a lower rate, depending on the severity of the side-effect.

5. Clinical observation will take place for at least 24 hours after replacing concentrations.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients must suffer from tonic or intermittent dystonia in one or more extremities.

2. Patients have an implanted programmable pump (SynchroMed® pump, Medtronic, Minneapolis MN, USA, 40 mL reservoir) for continuous IT drug administration.

3. Patients have shown an insufficient response to ITB at the usual flow rate, that is a <25% improvement on dystonia severity while ITB was administered to a level of at least 1000 µg/day or lower because of dose-limiting side effects.

4. Patients must report spontaneous dystonia of at least 5 on a numeric rating scale (0 represents no dystonia, 10 represents worst imaginable dystonia).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2008
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-04-2008
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	NL1224
NTR-old	NTR1269
Ander register	: P08.018
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A