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

Published: 18-02-2008
Last updated: 07-05-2024

Primary aim of the study is to compare the efficacy and safety of two flowrates of ITB while maintaining a constant daily dose.

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

Summary

ID

NL-OMON31522

Source
ToetsingOnline

Brief title
ITB flow rate study in CRPS I

Condition

- Movement disorders (incl parkinsonism)

Synonym
dystonia of enlarged muscletone

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: baclofen, CRPS I, flow rate, intrathecal

Outcome measures

Primary outcome

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

Secondary outcome

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.

Study description

Background summary

In a recent dose-escalation study of intrathecal baclofen (ITB), 48 patients who met a responsiveness criterion of 25% improvement as compared to placebo were implanted with a programmable pump for continuous administration of ITB. Surprisingly, only 65% of the 40 patients who actually received ITB reached a similar response at 1 year follow-up. One potential explanation for this finding is a prominent difference in applied flow rates between the screening and implantation study. The flow rate applied during the screening was a factor 6 higher than in the implantation study.
Hence increasing the flow rate of ITB infusion may result in an improved responsiveness of dystonia to this treatment.

Study objective

Primary aim of the study is to compare the efficacy and safety of two flowrates of ITB while maintaining a constant daily dose.

Study design

The ITB flow rate study is a double-blind randomized two-period cross-over study. Two different flow rates of ITB infusion are compared where one flow

rate is four times as high as the usual concentration of 3000 µg/ml. This is achieved by administering a concentration of 750 µg/ml baclofen while daily dose is kept unchanged. Each flow rate is maintained for 2 weeks in a double-blind randomized cross-over design. Safety and efficacy are evaluated by means of patient- and assessor-based evaluations.

Intervention

Intrathecal baclofen administered using a baseline flow rate (concentration 3000 microgr/ml) or 4 times higher (concentration 750 microgr/ml).

Study burden and risks

1. low-frequent visit to the hospital (in total 4 times, of which twice clinical observation for at least 24 hours)
2. low risk of malprogramming (not enlarged compared to the current clinical care)

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2300 RC Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2300 RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Patients must suffer from tonic or intermittent dystonia in one or more extremities.
•Patients have an implanted programmable pump (SynchroMed® pump, Medtronic, Minneapolis MN, USA, 40 mL reservoir) for continuous intrathecal drug administration.
•Patients have shown an insufficient response to intrathecal baclofen (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.
•Patients must report spontaneous dystonia of at least 5 on a numeric rating scale (0 represents no dystonia, 10 represents worst imaginable dystonia).

Exclusion criteria

Exclusion criteria are other causes of dystonia and pregnancy

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):	17-04-2008
Enrollment:	14

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	lioresal
Generic name:	baclofen
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-02-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2007-007436-25-NL
CCMO	NL21051.058.08