The BIRD study. Intrathecal Baclofen Infusion for Reflex Sympathetic Dystrophy related dystonia.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27484

Source
NTR

Brief title
The BIRD study

Health condition

Reflex sympathetic dystrophy (RSD) related dystonia.

Sponsors and support

Primary sponsor: Leiden University Medical Centre, Dept. of Neurology
Source(s) of monetary or material Support: Leiden University Medical Centre, Dept. of Neurology, and Medtronic Europe S.A., Switzerland

Intervention

Outcome measures

Primary outcome

1. GDS will be calculated separately at baseline (GDShome) and during a week at 1 year of follow-up. The difference between these two measurements is identified as the change from

baseline in GDS at 1-year follow-up (GDS1year);

2. Dystonia related functional limitations (DFL) are self-assessed at hourly intervals across the day using 4 items, addressing upper extremity function, capability of making transfers and mobility. Each item is assessed on a 0 – 3 scale. DFL will be calculated at baseline (DFLhome) and during a week at 1 year of follow-up.
The difference between these 2 measurements is identified as the change from baseline in DFL at 1 year follow-up (DFL1year).

Secondary outcome

1. RSD related impairments;

2. ADL and quality of life will be assessed separately before implantation and at 1-year follow-up;

3. The difference between these 2 measurements is identified as the change from baseline for each score.

Study description

Background summary

A single blinded placebo-run-in, dose-escalation design will be used to evaluate the efficacy of ITB.

After the screening phase a programmable pump for continuous ITB administration will be implanted in patients who are ITB responder.

This part of the study (implantation phase) is open with no placebo group.

Primary objective is to evaluate the efficacy and safety of ITB on tonic dystonia of RSD.

Secondary objectives are:

1. seek parameters of RSD and dystonia that predict responsiveness to ITB;

2. to study the differential ITB responsiveness of arm versus leg dystonia;

3. develop measures for the assessment of tonic dystonia during the screening phase and for the long-term evaluation after implantation.

Study objective

Dystonia associated with reflex sympathetic dystrophy responds markedly to intrathecal baclofen (ITB).

Study design

N/A

Intervention

Screening phase:

To evaluate the efficacy of ITB a percutaneous catheter is introduced into the lumbar subarachnoid space.

All patients will start with a 2-day placebo run-in, followed by a gradual titration of continuous intrathecal baclofen through an external pump. The daily baclofen dose will be increased according to a fixed schedule (200, 250, 300, 375, 450, 500, 600, 700 and 800 µg/24 hours).

Depending on the response, the duration of the screening procedure may vary from 1 to 2 weeks. If a baclofen-related side-effect occurs at a particular dose, then depending on the severity of the side-effect the pump will be stopped or adjusted to a lower infusion rate.

The outcome that is evaluated to determine if a patient will be implanted is the difference in change between global dystonia severity (GDS; visual analogue scale on which symptom severity is rated from 0 (absent) to 10 (most severe)) on ITB and placebo days.

This difference is calculated through the following steps:

1. GDSbaclo: for each ITB day the sumscore of 6 1-hour intervals (11.00 AM – 4.00 PM) is determined. Likewise, for the 2 placebo days a mean placebo-sumscore is calculated (GDSplacebo);

2. GDShome: a similar mean sumscore of 6 1-hour intervals of the GDS at home is determined;

3. For each day the GDS change score is calculated as follows:

GDSbaclo - GDShome = GDSchangescore1, expressed in % (calculated for each ITB day);
GDSplacebo - GDShome = GDSchangescore2, expressed in % (calculated for the mean of the 2 placebo days).

Criteria for being a candidate for pump implantation: a ≥ 25% difference between the GDSchangescore1 and GDSchangescore2 present on 2 subsequent days (responder).

Implantation phase:

After the screening phase a programmable pump (SynchroMed Infusion system, Medtronic INC, Minneapolis MN) for continuous ITB administration will be implanted in patients who fulfill the criteria stated above. During this phase ITB therapy will be started at a dose double the effective screening dose and will be titrated for a maximum effect over a 3-months period.

All implanted patients will be co-managed by the department of rehabilitation. Following implantation, severely affected patient will be referred to an in-patient rehabilitation unit. Mild to moderately affected patients will be seen in the out-patient rehabilitation unit.

Contacts

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Eligibility criteria

Inclusion criteria

1. All patients should fulfill the diagnostic criteria of the complex regional pain syndrome consensus report of the International Association for the Study of Pain (IASP):

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. All patients must suffer from tonic dystonia in 1 or more extremities, that may cause fixed postures at rest of variable severity;

3. Before starting the study all patients will have received a trial with oral baclofen. Only patients with an insufficient response or dose-limiting sedative effects to oral baclofen are eligible for this study.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-01-2002
Enrollment:	45
Type:	Actual

Ethics review

Positive opinion Date:	12-09-2005
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	NL364
NTR-old	NTR403
Other	: P01.098
ISRCTN	ISRCTN43633981

Study results

Summary results
N/A