

Intrathecal Baclofen Infusion for Reflex sympathetic Dystrophy related dystonia

Submission date 26/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/10/2008	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
P01.098; NTR403

Study information

Scientific Title

Acronym

The BIRD study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local ethics committee (Commissie Medische Ethiek) on the 2nd November 2001 (ref: P01.098).

Primary study design

Interventional

Study design

Part one: a single blinded placebo-run-in, dose-escalation design
Part two: thereafter, in responders, an open trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Reflex sympathetic dystrophy (RSD)

Interventions

Screening phase:

To evaluate the efficacy of ITB a percutaneous catheter is introduced into the lumbar subarachnoid space. All patients will start with a two-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 one to two 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 zero [absent] to ten [most severe]) on ITB and placebo days.

This difference is calculated through the following steps:

1. GDSbaclo: for each ITB day the sumscore of six one-hour intervals (11.00 a.m. - 4.00 p.m.) is determined. Likewise, for the two placebo days a mean placebo-sumscore is calculated (GDSplacebo)
2. GDShome: a similar mean sumscore of six one-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 two placebo days)

Criteria for being a candidate for pump implantation: a greater than or equal to 25% difference between the GDSchangescore1 and GDSchangescore2 present on two 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 three-month 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.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Intrathecal baclofen (ITB)

Primary outcome(s)

1. GDS will be calculated separately at baseline (GDSHome) and during a week at one year of follow-up. The difference between these two measurements is identified as the change from baseline in GDS at one-year follow-up (GDS1year)
2. Dystonia related Functional Limitations (DFL) are self-assessed at hourly intervals across the day using four items, addressing upper extremity function, capability of making transfers and mobility. Each item is assessed on a zero to three scale. DFL will be calculated at baseline (DFLhome) and during a week at one year of follow-up.

The difference between these two measurements is identified as the change from baseline in DFL at one year follow-up (DFL1year).

Key secondary outcome(s)

1. RSD related impairments
2. Activities of Daily Living (ADL) and quality of life will be assessed separately before implantation and at one-year follow-up

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

Completion date

01/01/2006

Eligibility

Key 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):

1.1. Continuing pain, allodynia or hyperalgesia, in which the pain is disproportionate to any inciting event

1.2. Evidence at some time of oedema, changes in skin blood flow, or abnormal sudomotor activity in the region of the pain

1.3. No condition that would otherwise account for the degree of pain and dysfunction

2. All patients must suffer from tonic dystonia in one 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/01/2002

Date of final enrolment

01/01/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Centre (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Industry

Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

Funder Name

Medtronic Europe S.A. (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration