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Intrathecal Baclofen Infusion for Reflex sympathetic Dystrophy related dystonia

Submission date 26/02/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 26/02/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 15/10/2008	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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).

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

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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).

Secondary outcome measures
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.

Overall study start date
01/01/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
45

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)
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Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration