Intrathecal baclofen treatment in dystonic cerebral palsy: A randomized clinical trial.

No registrations found.

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

Summary

ID

NL-OMON21127

Source
Nationaal Trial Register

Brief title
IDYS trial

Health condition

dystonia, dyskinesia, dystonic cerebral palsy, dyskinetc cerebral palsy, cerebral palsy, intrathecal baclofen, ITB

Sponsors and support

Primary sponsor: VU University Medical Center
Maastricht University Medical Center
Source(s) of monetary or material Support: Phelps Stichtig voor Spastici
Johanna KinderFonds
Kinderrevalidatiefonds de Adriaanstichting
RevalidatieFonds

Intervention

Outcome measures

Primary outcome

Goal Attainment Scaling.

Secondary outcome

1. Pediatric Evaluation of Disability Inventory;

2. Barry Albright Dystonia Scale;

3. Dyskinesia Impairment Scale;

4. Electromyography;

5. H-reflex;

6. Visual Analogue Scale for pain and comfort.

Study description

Background summary

Treatment optios for severe dystonic cerebral palsy is limited. Intrathecal baclofen treatment is used but the effects on the level of activities and participation remain unclear. Furthermore it is not know which patients benifit and which patients do not. With this multicenter, randomised controlled trial we aim to answer these questions.

Study objective

1. Intrathecal baclofen treatment in patients with dystonic cerebral palsy will improve daily activities and daily care, dystonia and spasticity;

2. Intrathecal baclofen treatment has no effect on independent functioning;

3. Patient characteristics such as location and severity of MRI lesions and Gross Motor Functioning Classification System (GMFCS) level might influence the effect of Intrathecal baclofen treatment in patients with dystonic cerebral palsy.

Study design

1. Baseline;

2. 3 months;

3. 1 year.

Intervention

Blinded treatment with ITB or placebo via an implanted micro-infusion pump (3 months). Followed by a 9 month follow up in which all patients receive ITB (unblinded).

Contacts

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Eligibility criteria

Inclusion criteria

1. Dystonic cerebral palsy;

2. Gross Motor Functioning Classification System (GMFCS) level IV or V;

3. Eligible for Intrathecal baclofen treatment using criteria of common practice;

4. Lesions on MRI (cerebral white matter, basal ganglia, central cortex);

5. Aged 4 to 25 years old;

6. Able and willing to complete study protocol;

7. Consensus about inclusion.

Exclusion criteria

1. Contra-indications for general anesthesia;

2. Contra-indications for baclofen;

3. Oral pharmacological treatment is sufficient;

4. Inadequate knowledge of Dutch or english language (parent and/or patient);

5. Deep brain stimulation;

6. Ventriculoperitoneal drain;

7. Other disorders interfering with treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	30-09-2012

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45097
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3510
NTR-old	NTR3642
CCMO	NL33312.029.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON45097

Study results

Summary results
N/A