Intrathecal baclofen treatment in dystonic cerebral palsy: a randomized clinical trial

Published: 05-04-2012
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Objectives: The primary aim of this study is to provide evidence for the effect of ITB treatment on the level of activities in dystonic CP patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON45097

Source
ToetsingOnline

Brief title
ITB in dystonic CP

Condition

- Congenital and peripartum neurological conditions

Synonym
cerebral palsy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: nog niet duidelijk,nog niet duidelijk

Intervention

Keyword: cerebral palsy, dyskinesia, dystonia, intrathecal baclofen

Outcome measures

Primary outcome

Main study parameters:

The primary outcome measurement is the effect on daily functioning and daily care measured by Goal Attainment Scaling.

Secondary outcome

Secondary outcome measurements include dystonia, spinal muscle activity and spasticity. Side effects will be monitored and we will study whether patient characteristics influence outcome.

Study description

Background summary

Dyskinetic cerebral palsy (CP) is mostly caused by damage to the basal ganglia and central cortex. Due to the dystonic movements the daily care of these patients can be difficult. Intrathecal baclofen ITB treatment has been suggested as a potential treatment for dystonia but the effects on daily activities are unknown and prospective data are needed to judge the usefulness of ITB in dystonic cerebral palsy.

Study objective

Objectives: The primary aim of this study is to provide evidence for the effect of ITB treatment on the level of activities in dystonic CP patients.

Study design

Study design: double blind placebo-controlled randomized clinical trial.

Intervention

Intervention: Group A will receive three months of continuous ITB treatment and group B will receive three months placebo treatment, both via an implanted pump.

Study burden and risks

We feel the risk and burden of participating in this study are relatively low. No extra risks are involved for subjects in the ITB treatment group. However, possibly higher risk for common complications occur for the subjects randomized to the placebo group.

Contacts

Public
Vrije Universiteit Medisch Centrum

Postbus 7057
Amsterdam 1007 MB
NL
Scientific
Vrije Universiteit Medisch Centrum

Postbus 7057
Amsterdam 1007 MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

-Dystonic cerebral palsy
-GMFCS IV or V
-Lesions on MRI (cerebral white matter, basal ganglia, central cortex)
-Aged 4 to 25 years old
-Able and willing to complete study protocol
-Consensus about inclusion

Exclusion criteria

-Contra-indications for general anaesthesia
-Contra-indications for baclofen
-Inadequate knowledge of Dutch language
-Deep brain stimulation
-Ventriculoperitoneal drain

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2013
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Baclofen
Generic name:	Baclofen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	05-04-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21127
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2010-019768-35-NL
CCMO	NL33312.029.10
OMON	NL-OMON21127

Study results

Date completed:	26-03-2019
Actual enrolment:	41