# 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.

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|---|---|
| **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

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

# Ethics review

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|---|---|
| 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: Nationaal Trial Register
Title:

## In other registers

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

# Study results

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