

# Effect of botulinum toxin treatment in children with cerebral palsy

<b>Submission date</b> 04/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/06/2008	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

### Contact name

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## Additional identifiers

### Protocol serial number

Stichting Bio-Kinderrevalidatie (PGO 01-0134); NTR41

## Study information

### Scientific Title

The effect of multi-level botulinum toxin treatment and intensive rehabilitation on walking ability in children with cerebral palsy

### Acronym

## The BOLIEN project

### Study objectives

Multi-level botulinum toxin-A (BTX-A) treatment of the lower extremities in combination with comprehensive rehabilitation leads to an improvement in mobility of children with cerebral palsy.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local ethics committee.

### Study design

Multicentre, randomised active controlled, parallel group trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Cerebral palsy (cerebral palsy)

### Interventions

Group A: multi-level BTX injections 6 weeks after the first assessment

Group B: multi-level BTX injections 30 weeks after the first assessment

#### Intervention:

Multi-level treatment with botulinum toxin A (BTX). Possible target muscles for a multi-level treatment are the psoas, medial/lateral hamstrings, hip-adductors, rectus femoris, triceps surae, and tibialis anterior/posterior unilateral or bilateral. Starting one week after the multi-level BTX-injections, the patients will be treated by a physiotherapist according to a standardised treatment protocol for 12 weeks.

#### Randomisation:

The patients will be randomised into two groups in a multiple baseline design. Follow-up measurements will be performed at 6, 12, 24 and 48 weeks.

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

Botulinum toxin

### Primary outcome(s)

1. Gross Motor Function Measure (GMFM)
2. Energy cost of walking

**Key secondary outcome(s))**

1. Spasticity of the treated muscles
2. Passive range of motion of lower extremity joints
3. Edinburgh Visual Gait score (GAIT)
4. Paediatric Evaluation Disability Inventory (PEDI), domain mobility
5. Problem score

**Completion date**

01/08/2006

**Eligibility****Key inclusion criteria**

1. Diagnosis of cerebral palsy (CP), hemiplegia or diplegia
2. Ability to walk with or without a walking aid, with or without an ankle-foot orthosis
2. Gait characterised by persistent flexion of the hip and knee in mid-stance when walking
3. Aged between 4 and 12 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

4 years

**Upper age limit**

12 years

**Sex**

All

**Key exclusion criteria**

1. BTX treatment in lower extremities 16 weeks before inclusion
2. Orthopaedic surgery 24 weeks before inclusion
3. Contra-indication for BTX-A
4. Contra-indication for general anaesthesia
5. Severe fixed contractures
6. Orthopaedic deformities, which have a bad influence on walking:
  - 6.1. (Sub)luxation of the hip with a migration index greater than 50 degrees
  - 6.2. Hip endorotation contracture greater than 15 degrees
  - 6.3. Flexion contracture of knee greater than 15 degrees
7. Presence of ataxia or dyskinesia
8. Other problems which have a negative influence on walking

**Date of first enrolment**

01/02/2001

**Date of final enrolment**

01/08/2006

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**P.O. Box 7057**

Amsterdam

Netherlands

1007 MB

## **Sponsor information**

**Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

**ROR**

<https://ror.org/00q6h8f30>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Princess Beatrix Funds (Prinses Beatrix Fonds) (The Netherlands)

**Funder Name**

Johanna Kinderfonds (The Netherlands)

**Funder Name**

Foundation for Paediatric Rehabilitation (Stichting Bio-Kinderrevalidatie) (The Netherlands)

# Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary  
Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes