

# Effects of Botulinum injections on the development of arm and hand function in children with unilateral spastic cerebral palsy

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<b>Registration date</b> 26/11/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/01/2014	<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

### Background and study aims

Children with unilateral spastic cerebral palsy often have impaired hand function. This study aims to find out if Botulinum toxin injections, training of hand function and use of a night splint gives a better improvement than training of hand function and use of a night splint alone.

### Who can participate?

Children with unilateral spastic cerebral palsy living in western Sweden.

### What does the study involve?

Children will be randomly allocated to one of two groups. One group will be treated with Botulinum toxin injections in the upper limb twice in one year, will use a night splint and will receive two 8-week intensive periods of occupational therapy in one year. The other group will receive occupational therapy. Investigations will take place before the start of the study and at 3, 6, 9 and 12 months after the start of the study.

### What are the possible benefits and risks of participating?

A benefit would be the close follow-up and focus on hand function. Possible risks would be adverse effects from Botulinum toxin in those allocated to receive injections.

### Where is the study run from?

The study is run from The Regional Rehabilitation Centre for Children and Adolescents at the Queen Silvia Childrens Hospital, Sweden.

### When is the study starting and how long is it expected to run for?

The study started in October 2004 and ran until August 2011.

### Who is funding the study?

The study is funded by several research foundations and The Health & Medical Care Committee of the Regional Executive Board, Region Västra Götaland and Göteborg & Södra Bohuslän, Sweden.

Who is the main contact?

Git Lidman, Occupational therapist, Queen Silvia Children's Hospital  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Kate Himmelmann

### Contact details

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## Additional identifiers

### Protocol serial number

151:109/01 (Medical Products Agency Sweden)

## Study information

### Scientific Title

Effects of Botulinum injections and occupational therapy on arm and hand function in children with unilateral spastic cerebral palsy compared to occupational therapy alone

### Study objectives

Botulinum toxin and occupational therapy increase hand function more than occupational therapy alone.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Medical Faculty University of Gothenburg, 11 January 2001, ref: Ö 177-00

### Study design

Randomized controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

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

## Unilateral spastic cerebral palsy

### Interventions

Upper limb Botulinum toxin injections twice in one year

Night splint

Occupational therapy: two 8-week intensive periods in one year

Twenty children (median age of 3 years 1 month) were randomly assigned to one of two groups of ten children each.

1. BoNT-A+OT group: Botulinum toxin injections in the upper limb twice in one year plus night splint plus two 8-week intensive periods of occupational therapy in one year
2. OT group: occupational therapy alone

All assessments performed by two occupational therapists who were aware of the child's intervention but were blinded to the previous measurements. A third occupational therapist scored the Assisting Hand Assessment (AHA) test, blinded to group allocation and order of assessments. Both groups had two 8-week blocks of therapy. This involved the implementation of a home program and a weekly session with an occupational therapist, intended to help the parents maintain and adjust the therapy. A static circular night splint was individually made.

Education and guidelines to the parents for the home program including: bimanual therapy (1h /day), splint (8h/night), manual stretching of the injected muscles and implementation of the goals in daily life (once/day), and a log book for documentation of treatment.

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome(s)

1. Range of motion (ROM) (active and passive) in the joints of the upper limb at baseline, 3, 6, 9 and 12 months
2. Assisting Hand Assessment (AHA) (capacity of hand activity) at baseline, 3, 6, 9 and 12 months
3. Canadian Occupation Performance Measure (COPM) (performance of hand activity) at baseline, 3, 6, 9 and 12 months
4. Covering all domains of ICF (International Classification of Functioning, Disability and Health) regarding the affected upper limb in children with unilateral spastic cerebral palsy

In the group randomized to Botulinum toxin injections at baseline and 6 months, the assessments were also made at 1 and 7 months, to capture the maximum effect of the injections.

### Key secondary outcome(s)

Range of movement (ROM), Assisting Hand Assessment (AHA), and Canadian Occupational Performance Measure (COPM) are performed, as well as documentation of hand surgery and Botulinum toxin treatment at 24, 26 48 and 60 months.

### Completion date

20/08/2011

## Eligibility

**Key inclusion criteria**

1. Unilateral spastic cerebral palsy with spasticity in the upper limb, typically in the pronator, thumb muscles and elbow flexors
2. Age 18 months to 10 years
3. Living in Västra Götaland

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

18 months

**Upper age limit**

10 years

**Sex**

All

**Key exclusion criteria**

1. Intellectual disability interfering with the intervention program
2. Upper limb dystonia
3. Previous upper limb surgery or Botulinum toxin injections

**Date of first enrolment**

25/10/2004

**Date of final enrolment**

20/08/2011

**Locations****Countries of recruitment**

Sweden

**Study participating centre**

**Box 210 62**

Göteborg

Sweden

SE 41804

# Sponsor information

## Organisation

Queen Silvia Children's Hospital (Sweden)

## ROR

<https://ror.org/00yqpgp96>

# Funder(s)

## Funder type

Government

## Funder Name

The Health & Medical Care Committee of the Regional Executive Board, Region Västra Götaland and Göteborg & Södra Bohuslän (Sweden)

## Funder Name

The Norrbacka-Eugenia and Folke Bernadotte Foundations (Sweden)

## Funder Name

The Sunnerdahl and Petter Silfverskiöld Foundations (Sweden)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration