

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

Submission date 26/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/01/2014	Condition category Nervous System Diseases	<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
git.lidman@vgregion.se

Contact information

Type(s)

Scientific

Contact name

Dr Kate Himmelmann

Contact details

Box 210 62
Göteborg
Sweden
SE 41804

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

25/10/2004

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

Age group

Child

Lower age limit

18 Months

Upper age limit

10 Years

Sex

Both

Target number of participants

20

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)

Sponsor details

c/o Dr Kate Himmelmann

Regional Rehabilitation Centre for Children and Adolescents

Box 210 62

Göteborg

Sweden

SE 41804

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00yqp96>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration