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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

Registration date
26/11/2013

Overall study status
Completed

Last Edited
08/01/2014

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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
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Sponsor type
Hospital/treatment centre

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

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