Effect of Botulinum Toxin A Injections and Specific Intensive Rehabilitation Therapy in Children with Hemiparetic Cerebral Palsy on Upper Limb Functions and Skills

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Objective: to determine whether botulinum toxin A (btA) injections, intensive bimanual skill training, or a combination of both leads to more and better use of the affected arm in hemiparetic children in play, leisure time, school and personal care...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON30186

Source
ToetsingOnline

Brief title
BoBiVa (Botuline toxine Bimanuele Vaardigheden)

Condition

- Congenital and peripartum neurological conditions

Synonym
congenital hemiparesis, Spastic hemiparetic cerebral palsy

Research involving
Human

Sponsors and support

Primary sponsor: Hoensbroek Revalidatiecentrum (HRC)
Source(s) of monetary or material Support: Ipsen Pharmaceuticals,Johanna KinderFonds;Phelps Stichting;Stichting ter behartiging der belangen van het gebrekkige kind.

Intervention

Keyword: Botulinum Toxin Type A, Cerebral Palsy, Motor skills, Upper Extremity

Outcome measures

Primary outcome

The Assisting Hand Assessment (AHA), a measurement instrument in which the performance and capacity of use of the affected hand in bimanual play is scored in a standardized way by video observation.

The most important bimanual goal for the child and their parents will be scored by Goal Attainment Scaling (GAS) and by video observation. Standardized video observation will also be used in scoring videos of two fine motor and one gross motor bimanual task.

These are all measurements at activity level of the International Classification of Functioning Disability and Health (ICF, WHO 2001).

Secondary outcome

Also measurements at ICF function level will be used like passive and active Range Of Motion (ROM), muscle strength, spasticity and movement velocity.

Study description

Background summary

Rationale: at the moment there is no sufficient evidence to support or refute the use of intramuscular injections of Botulinum toxin A (btA) as an adjunct to

managing the upper limb in children with spastic Cerebral Palsy (CP).

Rehabilitation therapy programs aimed at improving the performance and use of the affected hand in bimanual skills are not clearly defined. Evaluation of these therapy programs did not yet take place.

Study objective

Objective: to determine whether botulinum toxin A (btA) injections, intensive bimanual skill training, or a combination of both leads to more and better use of the affected arm in hemiparetic children in play, leisure time, school and personal care.

Study design

Study design: a factorial design with four study groups in which btA alone, intensive rehabilitation therapy aimed at improving bimanual skills alone, a combination of these two and continuing the regular therapy program will be compared to each other.

Intervention

In this study Dysport® will be used. For Dysport® (dilution 25U/0.1ml) three times the dose of Botox® will be taken: 6-9 U/kg bodyweight above elbow, 3-6 U/kg bodyweight in fore arm, limited to no more than 150 units at any one site. In the intrinsic thumb muscles the maximum dose will be 25U per muscle. A maximum Dysport® dose of 1000U/total bodyweight will be used in the present study.

The therapy programme for the children in group A and C consists of 3 times 30 minutes of physiotherapy and 30 minutes of occupational therapy, by experienced child therapists, 2 or 3 visites a week during 3 months.

Study burden and risks

The btA injections will be administered in the day care department of the hospital under general anaesthesia. No serious side effects of btA in the upper limb are reported until now. The rehabilitation therapy programme contains physiotherapy and occupational therapy half an hour each three times a week during 12 weeks. Six measurement sessions will take place in a period of 30 weeks, each lasting 3 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

•Age 2,5 - 12 years
•Cerebral Palsy
•Hagberg diagnosis: spastic hemiparesis or extreme asymmetric diplegia
•Hand function impairment Zancolli grade I with evident problems in thumb extension and supination, Zancolli grade IIA and IIB (Zancolli E.A., 1987)
•Mentally able to comprehend and perform tasks
•Children and their parents should be able to cope with the intensive rehabilitation therapy programme and the measurement sessions
•Children and the parents/caregivers should comprehend and speak Dutch
•Children and their parents indicate the necessity for improvement of the children*s abilities

Exclusion criteria

•Severe structural contractures of the muscles at the extremity to be treated (elbow extension deficit 20 degrees, supination deficit 45 degrees, deficit wrist dorsal flexion 30 degrees or more)
•Severe impairment of hand function, no active hand function is expected after treatment (Zancolli III)
•Hand surgery, phenolisation or btA injections in the arm less than nine months ago
•Contra indication for botulinum toxin (children with muscular diseases, like myasthenia gravis, tetanus vaccination less than 3 months before the injection, use of aminoglycoside antibiotics or spectinomycine, known hypersensitivity for human albumin)
•Contra indication for anaesthesia
•Children who cannot bare touching the affected arm and hand

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2008
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dysport

Generic name:	Botulinum toxin A
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	27-07-2006
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	17-12-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-002175-40-NL
CCMO	NL12005.096.06