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Effect of botulinum toxin A injections and specific intensive rehabilitation therapy in children with hemiparetic cerebral palsy on upper limb functions and skills

Submission date
04/12/2007

Recruitment status
No longer recruiting

Registration date
31/03/2008

Overall study status
Completed

Last Edited
20/08/2015

Condition category
Nervous System Diseases

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

Plain English Summary
Not provided at time of registration

Study website
http://www.srl.nl/default.asp?id=396&parent=0&template=algemeen.htm&sitecat=5

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL12005.096.06

Study information

Scientific Title
Effect of botulinum toxin A injections and specific intensive rehabilitation therapy in children with hemiparetic cerebral palsy on upper limb functions and skills

Acronym
BoBiVa (Botuline toxine Bimanuele Vaardigheden)

Study hypothesis
Research question:
What is the effect of botulinum toxin A (btA) injections (B), an intensive physical and occupational therapy program aimed at improving arm function and skills (C), or a combination of both (A), on arm function, bimanual skills and use of the affected arm, in children with hemiparetic cerebral palsy, relative to the course in such children who receive usual care (D)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical Ethics Committee of the Meuse Hospital (Medisch Ethische Toetsingscommissie Atrium MC-Maaslandziekenhuis), 27/07/2006
2. This trial is also registered at the Centrale Commissie Mensgebonden Onderzoek (CCMO) Central Committee for Research Involving Human Subjects (https://toetsingonline.ccmo.nl) (ref: NL12005.096.06)

Study design
Randomised 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

Condition
Cerebral palsy

Interventions
This study will take place in three hospitals in the Netherlands: University Hospital Maastricht (Franciscusoord Valkenburg), Maartenskliniek Nijmegen Hospital and Free University Medical Centre (Vrije Universiteit Medisch Centrum [VUMC]) Amsterdam.

Interventions:
Group A: BtA injections (Dysport®) prior to therapy programme and intensive physical and occupational therapy programme
Group B: BtA injections only
Group C: Intensive physical and occupational therapy programme
Group D: Usual care

BtA injections:
The most spastic muscles hampering function will be injected. Dysport® dilution: 25 U/0.1 ml, dose 6 - 9 U/kg body weight muscles above elbow, 3 - 6 U/kg body weight muscles in forearm, limited to no more than 150 units (0.6 ml) at any one injection site. In the intrinsic thumb muscles the maximum dose will be 25 U per muscle. A maximum Dysport® dose of 1,000 U per child in total per session will be used.

Intensive physical and occupational therapy programme:
Participants will receive one hour of ocupational therapy and 30 minutes of physical therapy, twice a week for 12 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Botulinum toxin A (Dysport®)

Primary outcome measure
1. Assisted Hand Assessment (AHA): original test kit for children 2.5 - 6 years and board game for children 7 - 12 years (T2, T4, T6)
2. A measure of manual ability for children with upper limb impairments (ABILHAND)-Kids questionnaire (T1 - T6)
3. Canadian Occupational Performance Measure (COPM): establishing treatment goals; Goal Attainment Scaling (GAS) of the most important bimanual treatment goal (T1, T4, T6)
4. Video recording of two fine motor tasks (children 7 - 12 years: buttering and cutting bread, screw construction task; children 2.5 - 6 years: building with 'poppons', threading beads) and one gross motor task (children 2.5 - 6 years: building blocks; children 7 - 12 years: stacking cylinders). These videos will be scored with newly developed and reliability tested Video Observation (VO) criteria (T2, T6).

T1 and T2: Baseline
T3: 6 weeks after btA and start of the therapy program
T4: 12 weeks, end of therapy program

T5: 18 weeks
T6: 24 weeks

Secondary outcome measures
1. Wrist and elbow tone and Tardieu Scale or Spasticity Test (SPAT): supine and sitting (T1 - T6)
2. Active and passive range of motion (ROM) of wrist (with fisted hand and with extended fingers), and of elbow and thumb (T1 - T6)
3. Grip strength: E-link (biometrics®) and functional grip strength (T1 - T6)

T1 and T2: Baseline
T3: 6 weeks after btA and start of the therapy program
T4: 12 weeks, end of therapy program
T5: 18 weeks
T6: 24 weeks

Overall study start date
01/01/2008

Overall study end date
01/01/2012

Eligibility

Participant inclusion criteria
1. Aged 2.5 - 12 years, either sex
2. Cerebral palsy
3. Hagberg diagnosis: spastic hemiparesis or extreme asymmetric diplegia
4. Hand function impairment Zancolli grade I with evident problems in thumb extension and supination, Zancolli grade IIA and IIB
5. Mentally able to comprehend and perform tasks
6. Children and their parents should be able to cope with the intensive rehabilitation therapy programme and the measurement sessions
7. Children and the parents/caregivers should comprehend and speak Dutch
8. Children and their parents indicate the necessity for improvement of the children's abilities

Participant type(s)
Patient

Age group
Child

Lower age limit
2.5 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
60 in total, 20 per participating centre

Participant exclusion criteria
1. Severe structural contractures of the muscles at the extremity to be treated:
1.1. Passive elbow extension maximum 160 degrees or less
1.2. Supination maximum 30 degrees or less from neutral position
1.3. Wrist dorsal flexion maximum 20 degrees or less in children aged 2.5 - 6 years, or 45 degrees or less in age group 7 - 12 years
2. Severe impairment of hand function: no active hand function is expected after treatment (Zancolli III)
3. Hand surgery or phenolisation or btA injections in the arm less than nine months ago
4. Contraindication for botulinum toxin (muscular diseases such as myasthenia gravis, tetanus vaccination less than three months before the injection, use of aminoglycoside antibiotics or spectinomycine and known hypersensitivity for human albumin)
5. Contraindication for anaesthesia
6. Children who cannot bear touching the affected arm and hand

Recruitment start date
01/01/2008

Recruitment end date
01/01/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Franciscusoord Child Rehabilitation
Valkenburg
Netherlands
6301 KA

Sponsor information

Organisation
Ipsen Biopharm Ltd (UK)

Sponsor details
Ashroad
Wrexham Industrial Estate

Wrexham
United Kingdom
LL13 9UF

Sponsor type
Industry

ROR
https://ror.org/00gmnqd91

Funder(s)

Funder type
Research organisation

Funder Name
Rotterdam Foundation Child Rehabilitation Fund 'Adriaan Fund' (Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting) (The Netherlands)

Funder Name
Johanna Children's Fund (Johanna Kinderfonds) (The Netherlands) - http://www.johannakinderfonds.nl

Funder Name
Phelps Foundation for Spasticity (Phelps Stichting voor Spastici) (The Netherlands) - http://www.phelps-stichting.nl

Funder Name
Profile Fund of the University Hospital Maastricht (Profileringsfonds azM) (The Netherlands)

Funder Name
Foundation for Children's Illness (Stichting het gebrekkige Kind) (The Netherlands)

Funder Name
Ipsen Biopharm Ltd (UK) - provided Dysport®

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/08/2015		Yes	No