ISRCTN35169306 https://doi.org/10.1186/ISRCTN35169306

Effect of botulinum toxin treatment in children with cerebral palsy

Submission date	Recruitment status	[ ] Prospectively registered
04/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/08/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/06/2008	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.vumc.nl/revalidatie/onderzoek

Contact information

Type(s)
Scientific

Contact name
Prof J.G. Becher

Contact details
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
+31 (0)20 444 0763
reva@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Stichting Bio-Kinderrevalidatie (PGO 01-0134); NTR41

Study information

Scientific Title
The effect of multi-level botulinum toxin treatment and intensive rehabilitation on walking ability in children with cerebral palsy

Acronym
The BOLIEN project

Study objectives
Multi-level botulinum toxin-A (BTX-A) treatment of the lower extremities in combination with comprehensive rehabilitation leads to an improvement in mobility of children with cerebral palsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee.

Study design
Multicentre, randomised active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cerebral parese (cerebral palsy)

Interventions
Group A: multi-level BTX injections 6 weeks after the first assessment
Group B: multi-level BTX injections 30 weeks after the first assessment

Intervention:
Multi-level treatment with botulinum toxin A (BTX). Possible target muscles for a multi-level treatment are the psoas, medial/lateral hamstrings, hip-adductors, rectus femoris, triceps surae, and tibialis anterior/posterior unilateral or bilateral. Starting one week after the multi-level BTX-injections, the patients will be treated by a physiotherapist according to a standardised treatment protocol for 12 weeks.

Randomisation:
The patients will be randomised into two groups in a multiple baseline design. Follow-up measurements will be performed at 6, 12, 24 and 48 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin

Primary outcome measure
1. Gross Motor Function Measure (GMFM)
2. Energy cost of walking

Secondary outcome measures
1. Spasticity of the treated muscles
2. Passive range of motion of lower extremity joints
3. Edinburgh Visual Gait score (GAIT)
4. Paediatric Evaluation Disability Inventory (PEDI), domain mobility
5. Problem score

Overall study start date
01/02/2001

Completion date
01/08/2006

Eligibility

Key inclusion criteria
1. Diagnosis of cerebral palsy (CP), hemiplegia or diplegia
2. Ability to walk with or without a walking aid, with or without an ankle-foot orthosis
2. Gait characterised by persistent flexion of the hip and knee in mid-stance when walking
3. Aged between 4 and 12 years

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
47

Key exclusion criteria
1. BTX treatment in lower extremities 16 weeks before inclusion
2. Orthopaedic surgery 24 weeks before inclusion
3. Contra-indication for BTX-A
4. Contra-indication for general anaesthesia
5. Severe fixed contractures
6. Orthopaedic deformities, which have a bad influence on walking:
6.1. (Sub)luxation of the hip with a migration index greater than 50 degrees
6.2. Hip endorotation contracture greater than 15 degrees
6.3. Flexion contracture of knee greater than 15 degrees
7. Presence of ataxia of dyskinesia
8. Other problems which have a negative influence on walking

Date of first enrolment
01/02/2001

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Faculty of Earth and Life Sciences
Institute of Health Sciences
De Boelelaan 1085

Amsterdam
Netherlands
1081 HV

Sponsor type
University/education

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Charity

Funder Name
Princess Beatrix Funds (Prinses Beatrix Fonds) (The Netherlands)

Funder Name
Johanna Kinderfonds (The Netherlands)

Funder Name
Foundation for Paediatric Rehabilitation (Stichting Bio-Kinderrevalidatie) (The Netherlands)

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