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

Effect of botulinum toxin treatment in children with cerebral palsy

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Gross Motor Function Measure (GMFM)
2. Energy cost of walking

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
12 years

Sex
All

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)

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

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes