Effect of botulinum toxin treatment in children with cerebral palsy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21315

Source
NTR

Brief title
The BOLIEN project

Intervention

Outcome measures

Primary outcome

1. Gross Motor Function Measure (GMFM);

2. Energy cost of walking.

Secondary outcome

1. Spasticity of the treated muscles;

2. Passive range of motion of lower extremity joints;

3. Edinburgh Visual Gait score (GAIT);

4. Pediatric Evaluation Disability Inventory (PEDI), domain ‘mobility’;

5. Problem score.

Study description

Background summary

National (dutch) multicenter trial;

Intervention:

Multilevel 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 standardized treatment protocol for 12 weeks.

Randomisation:

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

Uitkomstmaten (prim sec?):

Gross Motor Function Measure (GMFM), energy cost of walking, gait analysis, mobility questionnaire, spasticity, and passive range of motion of lower extremity joints.

Study objective

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.

Study design

N/A

Intervention

Group A will receive multi-level BTX injections 6 weeks after the first assessment, group B after 30 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis of cerebral palsy (CP), hemiplegia or diplegia, ability to walk with or without a walking aid, with or without an ankle-foot orthosis;

2. gait characterized by persistent flexion of the hip and knee in mid-stance when walking;

3. age between 4 and 12 years.

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 walking:

6.1 (Sub)luxation of the hip with a migration index > 50 degrees;

6.2 Hip endorotation contracture > 15 degrees;

6.3 Flexion contracture of knee > 15 degrees;

7. Presence of ataxia of dyskinesia;

8. Other problems which have a negative influence on walking.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2001
Enrollment:	47
Type:	Actual

Ethics review

Positive opinion

Date:	26-05-2005
Application type:	First submission

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
NTR-new	NL21
NTR-old	NTR41
Other	: Stichting Bio-Kinderrevalidatie (PGO 01-0134)
ISRCTN	ISRCTN35169306

Study results

Summary results
Arch Phys Med Rehabil. 2006 Dec;87(12):1551-8.