Effect of botulinum toxin treatment in children with cerebral palsy.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21315

Bron
NTR

Verkorte titel
The BOLIEN project

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2001
Aantal proefpersonen:	47
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-05-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL21
NTR-old	NTR41
Ander register	: Stichting Bio-Kinderrevalidatie (PGO 01-0134)
ISRCTN	ISRCTN35169306

Resultaten

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