Kosten-effectiviteit van combinatie behandeling botuline-toxine injecties en intensieve fysiotherapie bij kinderen met spastische Cerebrale Parese.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27016

Source
Nationaal Trial Register

Brief title
SPACE BOP

Health condition

NL: (kosten-)effectiviteit, spastische cerebrale parese, botuline toxine, intensieve functionele fysiotherapie.

EN: (cost-)effectiveness, spastic cerebral palsy, botulinum toxin, intensive functional physiotherapy.

Sponsors and support

Primary sponsor: Erasmus MC, dept. Rehabilitation Medicine
PObox 2040, 3000 CA Rotterdam
The Netherlands
Source(s) of monetary or material Support: ZonMW doelmatigheidsonderzoek (2009)

Intervention

Outcome measures

Primary outcome

Primary measures are:

1. Functional health status as measured by the Child Health Questionnaire (CHQ) Child and Parent Forms;

2. A condition-specific DISABKIDS health related quality of life questionnaire for CP;

3. The level of actually performed everyday physical activities (‘actual performance’) as measured with valid and reliable several-day ambulatory monitoring techniques;

4. Gross motor functioning as measured using the Gross Motor Function Measure (GMFM66).

Cost-utility analyses will be done using costs per quality adjusted life year (QALY) as primary outcome measure. The Health Utilities Index (HUI) will be the primary outcome measure for the economic evaluation.

Secondary outcome

1. Instrumented clinical gait analysis (‘actual capacity’) using video observation, force platform, and EMG measurements;

2. (Perceived changes in) functional activities will be measured with the Pediatric Evaluation of Disability Inventory (PEDI);

3. Spasticity, as measured with a modified Tardieu scale;

4. Muscle force (or weakness) will be measured using an isometric hand-held dynamometer;

5. Muscle length / passive range of motion will be measured in standardized postures using a goniometer;

6. Pain intensity will be measured using a Visual Analogue Scale (VAS) for children.

Study description

Background summary

Spastische Cerebrale Parese (CP) is de grootste groep in de kinderrevalidatie en betreft persisterende houdings- of bewegingsstoornissen leidend tot (ernstige) beperkingen in het functioneren. Jonge
kinderen met CP worden vaak behandeld met multilevel botuline-toxine-A (BtA) injecties in combinatie met intensieve oefen/fysiotherapie (iFT). Eerdere effectiviteitsbepalingen van deze dure interventie richtten zich op veranderingen van stoornissen, op de via gangbeeldlaboratoria gemeten functionele
capaciteit, op grof motorische vaardigheden (GMFM), of op zelf-gerapporteerde ervaren beperkingen.
Echter, met deze uitkomstmaten weten we niet of kinderen na behandeling ook daadwerkelijk minder beperkt zijn in het dagelijks functioneren. De effectiviteit van BtA-iFT behandeling en de meerwaarde
van BtA injecties zijn nog nooit uitgedrukt in verbeteringen van het daadwerkelijke activiteiten niveau in de dagelijkse leefsituatie, terwijl dit voor alle betrokkenen juist ultiem behandeldoel is en van primair
belang voor doelmatigheid. Ook is de effectiviteit van BtA-iFT op kwaliteit van leven niet onderzocht, evenmin als de kosteneffectiviteit. Ons doel is middels een RCT met 2 groepen de lange termijn
(kosten)effectiviteit te vergelijken van BtA injecties met iFT en alleen iFT behandeling. Het daadwerkelijke activiteiten niveau, kwaliteit van leven en GMFM zijn primaire uitkomstmaten voor doelmatigheid, secundair zijn gebruikelijke valide uitkomstmaten voor CP (GMFCS, PEDI, gangbeeldanalyse). Het intention-to-treat
principe wordt gevolgd. Covariantieanalyses worden gedaan verschil in verandering te vergelijken tussen groepen, evenals subgroep analyses voor leeftijd en motorisch functioneren op baseline.

Study objective

We aim to determine the effectiveness and cost-effectiveness of multilevel botulinum-toxin type A injections in combination with a 12-week period of intensive functional physiotherapy exercises (BtA+iPT) and compare this with the effectiveness and cost-effectiveness of only a 12-week period of intensive functional physiotherapy exercises (iPT) in young children with
spastic Cerebral Palsy (4-12 years).

Study design

1. Preparation trial period 01-2009 until 06-2009;

2. Inclusion period 07-2009 until 09-2010;

3. Data analysis and publication 09-2010 until 12-2011.

Intervention

A 2-group RCT will be conducted: one intervention group will receive combined multilevel

BtA+iPT treatment (multiple botulinum toxin injections followed by a 12-week period of intensive physiotherapy
exercises according to a standardized protocol of on average 4 hours per week) and the other intervention group will only receive the iPT component as treatment. The children will be recruited via (waiting lists of) the BtA-consulting hours in Amsterdam and Rotterdam, and when necessary via affiliated CP treatment centers in the Netherlands. The current BtA-iPT intervention protocol is standardized.

Contacts

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Eligibility criteria

Inclusion criteria

1. Spastic cerebral palsy;

2. Aged 4-12 years;

3. Lower extremity primarily involved;

4. GMFCS levels I-III;

5. Sufficient motor selectivity.

Exclusion criteria

1. Surgery < 12 months before study;

2. BtA treatment < 6 months before study;

3. Severe contractures;

4. Cognitively unable to follow instructions;

5. Co-morbidity affecting everyday functioning.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-02-2009
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	NL1576
NTR-old	NTR1655
Other	ABR/EudraCT : 26738/2009-009868-31
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A