Standardized physical therapy for cervical dystonia.

Gepubliceerd: 10-05-2012 Laatst bijgewerkt: 18-08-2022

Disability due to Cervical Dystonia will be more reduced by Botulinum toxin injections in combination with PT according the treatment guideline than by BTX injections in combination with regular PT.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25897

Bron
NTR

Aandoening

Cervical dystonia, physical therapy,botulinum toxin, disability, functional status

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam, University Medical Center Groningen, Leiden University Medical Center
Overige ondersteuning: - Department of exercise therapy, Amsterdam School of Health Professions

- Scientific fund of the Dutch Dystonia Patient Association

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Disability, measured with the Toronto Western Spasmodic Torticollis Rating Scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Cervical Dystonia (CD) is characterized by involuntary muscle contraction of the neck and abnormal positions of the head that affects daily life activities and social life of patients. Patients are usually treated with botulinum toxin injections into the neck muscles to decrease the abnormal head postures and pain. In addition, many patients are referred for physiotherapy with the aim to improve their functioning in daily life. A recent systematic review on allied health interventions in CD shows a lack of intervention studies that underpin or refute the effectiveness of physical therapy.

Study objectives:

Our main goal is to evaluate the effectiveness and cost-utility of a standardized physical therapy (PT) programme compared with regular physiotherapy, both as add-on treatment to BTX-injections, on the ability of CD patients to perform everyday activities.

Study design:

Multi-centre Single blind Randomized Controlled Trial.

Study population:

100 patients with idiopathic cervical dystonia treated with botulinum toxin injections.

Primary outcome:

The primary outcome is disability in daily functioning, assessed with the disability subscale of the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) after one year. The primary outcome for the economic evaluation is the costs per quality adjusted life-year.

Intervention:

Patients in the intervention group will receive Botuline Toxin (BTX) injection combined with a standardized PT program for 12 months according to the best evidence- / best practice treatment guideline. Interventions will be provided by specially trained therapists. Patients in the control group will receive BTX injections in combination with 12 months regular PT.

Measurements:

All data will be collected at baseline, after six months and after one year. In order to determine the additional effects of a PT program, measurements will be performed just before the botuline injections when botuline has the least effect on the symptoms of dystonia . Measurements will be performed by an independent blind assessor.

Expected results:

It is expected that disability due to CD will be more reduced by BTX injections in combination with a standardized PT programme according the treatment guideline than by BTX injections in combination with regular PT.

Doel van het onderzoek

Disability due to Cervical Dystonia will be more reduced by Botulinum toxin injections in combination with PT according the treatment guideline than by BTX injections in combination with regular PT.

Onderzoeksopzet

Baseline, after six months and 12 months.

Onderzoeksproduct en/of interventie

Patients in the intervention group will receive Botuline Toxin (BTX) injection combined with a standardized PT program for 12 months consisting of muscle stretching, artherogenic mobilistions and excersize therapy. Interventions will be provided by specially trained therapists.

Patients in the control group will receive BTX injections in combination with 12 months regular PT provided by common Dutch pracices.

Contactpersonen

Publiek

AMC, Department of Neurology
Meibergdreef 9
P.O box 22660
J. Dool, van den
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663614

Wetenschappelijk

AMC, Department of Neurology
Meibergdreef 9
P.O box 22660
J. Dool, van den
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663614

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 100 patients with idiopathic CD;

2. 30 years or older;

3. Treated with botulinum toxin.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Secondary (including psychogenic) dystonia;

2. Hereditary (dominant) forms of dystonia;

3. Segmental, hemi-, multifocal or generalized dystonia;

4. Patients who underwent neurosurgery;

5. Inability to understand written and spoken Dutch language;

6. Patients treated with the Bleton method by their physiotherapist at the moment of inclusion.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-1012
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-05-2012
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	NL3291
NTR-old	NTR3437
Ander register	METC AMC : 2012_048
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A