Standardized physical therapy for cervical dystonia.

No registrations found.

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

Summary

ID

NL-OMON25897

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam, University Medical Center Groningen, Leiden University Medical Center
Source(s) of monetary or material Support: - Department of exercise therapy, Amsterdam School of Health Professions

- Scientific fund of the Dutch Dystonia Patient Association

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Severity of dystonie, with the TSUI scale;

2. Pain, with a numeric rating scale;

3. Quality of life, with the Craniocervical dystonia Questionnaire 24;

4. Anxiety and depression with the Beck anxiety and depression inventory;

5. Healthcare costs and health utility with Quality Adjusted Life Years (QALY).

Study description

Background summary

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.

Study objective

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.

Study design

Baseline, after six months and 12 months.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. 100 patients with idiopathic CD;

2. 30 years or older;

3. Treated with botulinum toxin.

Exclusion criteria

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.

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):	01-09-1012
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-05-2012
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	NL3291
NTR-old	NTR3437
Other	METC AMC : 2012_048
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A