Botulinum Neurotoxin (BoNT) as new treatment for functional (psychogenic) jerky movement disorders.

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Therapy of psychogenic jerks currently focuses on frequently co-occurring psychiatric disease, but results are poor. In this project, we will study the effect of BoNT on movement disorders of psychogenic origin in a mono centred randomised…

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

Samenvatting

ID

NL-OMON26050

Bron
NTR

Aandoening

Botulinum neurotoxin (BoNT) has emerged as a useful therapy for several movement disorders associated with muscle overactivity such as dystonia and jerky movement disorders. At least 2–9% of patients seen in movement disorder clinics suffer from movement disorders with a psychogenic origin and a substantial part of them has jerks. These psychogenic jerky movement disorders cannot be accounted for by a known neurologic syndrome.

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess whether treatment with BoNT leads to improvement of psychogenic jerks according to an independent movement disorder specialist assessed with the Clinical Global Impression - Improvement scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Botulinum neurotoxin (BoNT) has emerged as a useful therapy for several movement disorders associated with muscle overactivity. At least 2–9% of patients seen in movement disorder clinics suffer from movement disorders with a psychogenic origin and a substantial part of them has jerks. These psychogenic jerky movement disorders cannot be accounted for by a known neurologic syndrome. Therapy of psychogenic jerks currently focuses on frequently co-occurring psychiatric disease, but results are poor. In this project, we will study the effect of BoNT on movement disorders of psychogenic origin.

Objective:

To evaluate the effect of treatment with BoNT on psychogenic jerks.

Study design:

A monocenter study consisting of two parts: a double-blind randomized placebo controlled

intervention study of 16 weeks and an uncontrolled follow-up study of one year to evaluate the long-term effects of BoNT.

Study population:

Patients with at least one invalidating consistent type of psychogenic jerk that is present for 1 year or longer.

Intervention:

During the trial phase of the study, patients will receive two BoNT or placebo injections with an interval of 3 months. The number of muscles injected and the doses to be administrated in an individual patient will be determined by an experienced neurophysiologist analogous to treatment of dystonia. Hereafter, for the follow-up study all patients will receive 4 BoNT injections at intervals of 3 months.

Main study parameters/endpoints:

Primary outcome measure: To assess whether treatment with BoNT leads to improvement of psychogenic jerks according to an independent movement disorder specialist assessed with the Clinical Global Impression - Improvement scale.

Secondary outcome measures are the effect of BoNT on: the severity of jerks according to a movement disorder specialist; improvement and severity of the jerk according to the patient; nature and severity of overall dyskinesia; jerk frequency; whether patients consider treatment with BoNT effective; disability; quality of life; co-existent psychiatric disorders and the occurrence of adverse reactions; muscle weakness

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The risks associated with participation in this study are low: BoNT is considered a safe therapy in other movement disorders. The most common side effects of BoNT are local weakness and pain and side effects are reversible. The neuropsychological and psychiatric questionnaires used in our study are considered to be mildly psychologically stressful.

Doel van het onderzoek

Therapy of psychogenic jerks currently focuses on frequently co-occurring psychiatric

disease, but results are poor. In this project, we will study the effect of BoNT on movement disorders of psychogenic origin in a mono centred randomised controlled trial. The study consists of two parts: a double-blind randomized placebo controlled intervention study of 16 weeks and an uncontrolled follow-up study of one year to evaluate the long-term effects of BoNT. Hypothesis is that administration of BoNT is an effective treatment for jerky psychogenic movement disorders that significantly compromise patients.

Onderzoeksopzet

Baseline (T = 0):

1. Neurological examination, recorded on video;

2. Psychiatric interview, recorded on video;

3. Questionnaires (psychiatry, disability and tic assessment);

4. CGI – severity by examiner (based on video) and patient;

5. Counting of the amount of jerks during 10 minutes of the psychiatric interview on video;

6. AIMS and PMD scale scores based on the recorded video during neurological examination.

T= 16 weeks:

1. Neurological examination, recorded on video;

2. Psychiatric interview, recorded on video;

3. Questionnaires (psychiatry, disability and tic assessment);

4. CGI – severity by examiner based on video neurological examination;

5. CGI-improvement relative to T = 0 by examiner based on video neurological examination;

6. Counting the amount of jerks during 10 minutes of the psychiatric interview on video;

7. AIMS and PMD scores based on the recorded video during neurological examination;

8. Interview (treatment effective, placebo or BoNT, CGI-S, CGI-I, VAS, adverse events);

9. MRC weakness.

T = 16 months:

1. Neurological examination, recorded on video;

2. Psychiatric interview, recorded on video;

3. Questionnaires (psychiatry, disability and jerk assessment);

4. CGI – severity by examiner based on video neurological examination;

5. CGI-improvement relative to T=0 and T=16 by examiner based on video neurological examination;

6. Counting the amount of jerks during 10 minutes of the psychiatric interview on video;

7. AIMS and PMD scale scores based on the recorded video during neurological examination;

8. Interview (treatment effective, CGI-S, CGI-I, adverse events);

9. MRC weakness.

Onderzoeksproduct en/of interventie

Patients will be randomized to treatment with:

1. 2 times injections with botulinum neurotoxin injections intramuscular with a 3 month interval, or;

2. 2 times injections of placebo intramuscular with a 3 month interval.

Placebo will consist of 0.9% sterile saline. This is a frequently used placebo in studies on botulinum toxin.
After the trial period, all patients will receive 4 injections of BoNT also with 3 month intervals.

For individual patients, the dose of botulinum toxin to be injected will be determined based on the number and type of muscles that are involved in performing the jerk. The muscles that will be injected will be determined by a neurophysiologist experienced in treatment with BoNT according to the pattern of movements visible and according to the involved muscles measured with EMG. The dosage of BoNT depends on the volume of the muscle(s) it is injected in. Guidelines for starting dosages and for adjustments after the first injection for individual muscles exist. These guidelines will be used for the treatment of psychogenic jerks in this study. Because the dosage of BoNT depends on the muscles to be injected, individual patients will receive different dosages. The dilution volume of Dysport will be 500 units in 2.5 cc of 0.9% saline. The maximum dosage per treatment session is 400 Dysport units. BoNT is an accepted and widely-used therapy for dystonia and as such a great deal of experience is available.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with at least one invalidating consistent type of psychogenic jerk that is present for 1 year or longer.
Patients with one consistent type of invalidating tremor present for one year or longer .

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years or > 80 years;

2. Psychogenic jerk of interest present for < 1 year;

3. Treated with BoNT two or more times in the past year;

4. Pregnancy;

5. Coagulation disorders;

6. Insufficient knowledge of Dutch language;

7. Legally incompetent adult;

8. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	07-03-2011
Aantal proefpersonen:	54
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	24-08-2010
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	NL2371
NTR-old	NTR2478
Ander register	MEC Academic Medical Centre : 10/079
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A