Botulinum toxin as a new treatment modality for jerky psychogenic movement disorders: a monocenter randomized controlled trial

Published: 09-04-2010
Last updated: 18-07-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON34213

Source
ToetsingOnline

Brief title
Botulinum neurotoxin as treatment in psychogenic jerks

Condition

- Movement disorders (incl parkinsonism)

Synonym
conversion disorder, functional movement disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Fonds

Intervention

Keyword: Botulinum neurotoxin, Movement disorders, Psychogenic disease, Trial

Outcome measures

Primary outcome

Primary outcome measure:

The improvement of motor characteristics of the jerk of interest assessed with the Clinical Global Impression - Improvement scale by an independent movement disorder specialist;

Secondary outcome

Secondary Objectives:

To asses, in patients with psychogenic jerks, the effect of treatment with BoNT on:

* the severity of the invalidating jerk of interest scored by a movement disorder specialist;

* improvement of motor characteristics and severity of the invalidating jerk of interest scored by the patient;

* the nature, distribution and severity of overall dyskinesia, scored by a movement disorder specialist;

* the frequency of the invalidating jerk of interest;

* whether patients consider treatment with BoNT effective and whether they judge that the benefits of treatment outweigh the side-effects;

* disability;

* quality of life;

* co-existent psychiatric disorders;

* the occurrence of adverse reactions;

* muscle weakness.

Study description

Background summary

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 psychogenic movement disorders. These are disorders that cannot be accounted for by a known neurologic syndrome. A substantial part of these patients has jerks. 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.

Study objective

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

Study design

We will perform a monocentre study. This 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.

Intervention

During the trial phase of the study, patients will receive up to two BoNT or placebo injections. 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. For the follow-up study, all patients will be assigned to treatment with BoNT at intervals of approximately 3 months until 12 months after the end of the trial period.

Study burden and risks

The risks associated with participation in this study are low: BoNT is considered to be a safe therapy in other movement disorders. The most common side effects of BoNT are local weakness and pain. These side effects are

reversible. The neuropsychological and psychiatric questionnaires used in our study are considered to be mildly psychologically stressful.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Eligible patients for the study have at least one consistent type of jerk of psychogenic origin. Two movement disorder specialists have to agree on the diagnosis based on clinical characteristics and on additional investigations if considered necessary. The diagnosis of psychogenic jerks needs to have a *definite* or *probable* level of certainty for psychogenic movement disorders. The jerk of interest has to significantly disable the patient in his/her daily functioning according to the patient and the movement disorder specialists and needs to be performed by a muscle or muscles amendable to injection. The jerk of interest may be simple or complex if only treatment with BoNT is considered possible.

Exclusion criteria

* Age < 18 years or > 80 years;
* Psychogenic jerk of interest present for < 1 year;
* Previous or current treatment with BoNT;
* Legally incompetent adult;
* Pregnancy;
* Coagulation disorders;
* Insufficient knowledge of Dutch language
* No informed consent

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2011
Enrollment:	54
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dysport
Generic name:	Botulinum neurotoxin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	09-04-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-019338-29-NL
CCMO	NL32103.018.10

Study results

Results posted:	19-01-2016
Actual enrolment:	50

First publication
01-01-1900