High-Density Surface EMG Guided Botulinum Toxin Injection - Effect on the Compound Muscle Action Potential Recorded from the Extensor Digitorum Brevis Muscle

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

Summary

ID

NL-OMON30657

Source
ToetsingOnline

Brief title
HD-sEMG guided Botulinum Toxin injection

Condition

- Movement disorders (incl parkinsonism)

Synonym
n.a.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ipsen Farmaceutica B.V.

Intervention

Keyword: Botulinum Toxin High-Density EMG dosis

Outcome measures

Primary outcome

Reduction of the compound muscle action potential (CMAP) measured from the extensor digitorum brevis (EDB) compared between study and control side after 2 weeks.

Secondary outcome

Timecoarse after 8 en 12 weeks is evaluated to see if this differs between the two sides.

Study description

Background summary

The effect of Botulinum Toxin (BTX) is based on the neuromuscular blockade of cholinergic fibers of the peripheral nervous system. Since the introduction of BTX type A (BTXA) into therapeutic medicine, the use of this drug has been widely expanded to many medical disciplines and indications. Clinical observations and experimental studies revealed an effect of BTX not only on the target muscle, but also on adjacent (untreated) muscles. Experimental studies have proven that local peripheral diffusion of BTX is a major causative factor for this side-effect. Peripheral diffusion is mainly a problem in areas in which multiple muscles have a close topographical relationship, as e.g. in the face and neck. Limiting the dose of BTX in such critical anatomical areas has turned out to be helpful in reducing untoward spread of toxin to other muscles (called *toxin jump*). A plausible strategy to reduce the side-effect problem without diminishing the efficacy of BTX in the target muscle is to inject a lower dose of the toxin only in the area of its action (i.e. in the endplate region). High-density surface electromyography (HDsEMG) allows a precise and

reliable endplate zone localization. Using this electrophysiological technique, endplate zone locations and distributions could be successfully specified in several muscle groups. Using a recently developed HDsEMG electrode grid, BTX injection is even possible through holes in between the sensor so that marking of the endplate zone and removal of the grid prior to injection is not necessary.

Study objective

The aim of this pilot study is to evaluate whether precise HDsEMG-guidance improves the therapeutic effect of BTXA. Because of its minor functional importance and focused endplate distribution, the extensor digitorum brevis (EDB) muscle is selected for this investigation. Moreover, this muscle has already shown in previous studies to be suitable for such a model. To achieve only a local toxin administration, only a minimal effective dose of the toxin will be administered (from a higher dose we would not expect a positive effect of precise administration near the endplates due to diffusion of the drug throughout the main part of the muscle). As a gradual measure of the therapeutic effect of the toxin, we compare changes in the amplitude of the compound muscle action potential (CMAP) in response to supra-maximal stimulation of the peroneal nerve.
We hypothesize, that with a precise injection in the endplate region, a better therapeutic effect can be achieved than on the control site in which an injection of the same dose into the (anatomically defined) center of the EDB muscle is performed.

Study design

1. In a preliminary experiment (4 subjects) we will verify if a dose of 30 IU actually leads to a +/- 50% CMAP amplitude reduction measured at day 30 after HDsEMG guided BTXA injection in endplate region of the EDB muscle (as can be expected from previous studies).
2. Control study of the therapeuthic effect of BTXA injection with HD-sEMG guidance (study side) and without HD-sEMG guidance (contralateral muscle of the same subject). Subjects are followed longitudinally on 4 occasions (baseline, week 2, 8, and 12) to consider the time-dependent effect of BTXA.

Intervention

On the study side the injection of BTXA takes place under guides of HDsEMG. On the control side this is done without the knowledge of where the endplate position is.

Study burden and risks

The EDB muscle is of little use in daily life. A reduction in the force of this

muscle has no functional impact for the participant. BTXA injection in the EDB muscle has no known risks involved. The measurement of the CMAP involves electrical stimulation of the nerve. This is a standard clinical technique that causes negligible discomfort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Obtainable CMAP from the extensor digitorum brevis muscle

Exclusion criteria

neuromuscular disorders

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2007
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL15737.091.07