Effect of botulinum toxin (BoNT-A) injections on intrinsic and reflexive contributions to ankle joint resistance for patients with spasticity.

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

Summary

ID

NL-OMON48057

Source
ToetsingOnline

Brief title
Effect BoNT-A on spasticity.

Condition

- Movement disorders (incl parkinsonism)

Synonym
cerebrovascular accident / Spinal cord injury, myelophathy, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Sint Maartenskliniek

Source(s) of monetary or material Support: Technologiestichting TTW

Intervention

Keyword: Botulinum toxin (BoNT-A), Joint resistance, Motorized assessment, Spasticity

Outcome measures

Primary outcome

The primary study parameter is the reflexive joint resistance measured across 3 sessions.

Secondary outcome

The secundary study parameters are the reflexive and intrinsic joint resistance measured across 3 sessions.

Study description

Background summary

Spasticity is a common syndrome caused by various brain and neural injuries with several negative consequences, e.g. impaired walking ability and functional independence. Botulinum neurotoxin type A (BoNT-A) injections are a frequently used clinical intervention for the reduction of muscle tone and spasticity. The current clinical evaluation of the effect of BoNT-A has mainly been assessed using the Modified Ashworth Scale (MAS). Unfortunately, the MAS can only be used to assess muscle tone, and it has a questionable reliability and low responsiveness to change. Thus, the clinical effect and cost-effectiveness of spasticity treatment using BoNT-A is not well investigated nor understood, while BoNT-A injections are actively used as clinical intervention. To get increased insight into the beneficial and adverse effects of BoNT-A interventions, it is important to quantify the effect of BoNT-A interventions on the different contributions to joint (hyper-)resistance. Thus, potentially improving clinical decision making and cost-effectiveness.

The state-of-the-art to quantify the different contributions to joint resistance to investigate BoNT-A interventions is based on musculoskeletal modelling. These methods model the musculoskeletal system based on previously investigated characteristics of smaller elements of the system and as such use

a large number of a-priori assumptions. The lack of a golden standard, makes it difficult to understand whether the published (conflicting) results are due to reality or erroneous models. Therefore, we propose to use a system identification technique to separate spasticity (reflexive ankle joint resistance) from the combination of muscle tone and tissue properties (intrinsic ankle joint resistance). System identification methods build a model of the musculoskeletal system directly from an experimental dataset. This dataset is obtained in a dedicated experiment in which the ankle joint is externally perturbed by a motor and the subsequent biomechanical response, i.e. the resistance to these perturbations, is analyzed. Main benefit of the proposed method is that it only relies on a single biological assumption, namely that the ankle stretch reflex has a 40ms neural delay. The validity to use the system identification methodology as pre-posttest assessment technique to quantify the effect of clinical interventions on joint resistance has been shown in several studies.

Study objective

The main objective of the study is to evaluate the effect of BoNT-A injections on the intrinsic an reflexive contributions to ankle joint resistance for patients with spasticity. We hypothesize that, with respect to baseline, reflexive joint resistance should be decreased 6 weeks after injection, while returning back to baseline values after 12 weeks.

Study design

This is an one-site study with a pre-posttest design. The study consists of 3 sessions: 1 session pre-intervention and 2 sessions (6 and 12 weeks) post-intervention.

Study burden and risks

The study does not create direct benefits for the subjects, as the protocol just adds observational experiments on top of regular clinical care. The burden is minimal and the risks negligible, as the protocol consists of 10 minutes of preparation and 25 minutes of non-invasive tests. Moreover, 2 out of 3 visits will be combined with regular clinical appointments to further minimize the burden. In total, subjects will participate in 3 sessions over a 12 week period. Similar test with the ankle dynamometer used have already been executed/approved multiple times by the METC.

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

- a minimum of 6 months post-lesion/post-stroke to ensure that the participant has a stable neurological condition, without clinical alterations
- age 18 years or older at the time of the study
- spasticity of any/all of the m. triceps surae, i.e. have a MAS/Tardieu score * 1
- have an ankle joint range of motion of at least 20° in the sagittal plane
- ability to make a transfer on to the Achilles (medical device)
- current treatment of any/all of the m. tricpes surae with BoNT-A for spasticity reduction

Exclusion criteria

- have a MAS/Tardieu score of 4
- receive BoNT-A combined with other therapies aimed at reducing spasticity

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2020
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Achilles
Registration:	No

Ethics review

Approved WMO

Date:	18-02-2020
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
CCMO	NL71757.029.19