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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26235

Source
NTR

Brief title
Reflexioning

Health condition

Spinal Cord Injury and Stroke

Sponsors and support

Primary sponsor: Sint Maartenskliniek Research
Source(s) of monetary or material Support: NWO Toegepaste en Technische Wetenschappen (TTW)

Intervention

Outcome measures

Primary outcome

Reflexive joint resistance (Nm/rad/s)

Secondary outcome

Intrinsic joint resistance (Nm/rad)

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 model 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.
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. Secondary objectives are to examine the (across-subject) effect of the number of BoNT-A injections on the difference in reflexive ankle joint resistance and the difference in intrinsic ankle joint resistance before and 6 weeks after injection.

Study objective

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

T0: Prior to the botox injections
T1: 6 weeks after the botox injections
T2: 12 weeks after the botox injections

Contacts

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Eligibility criteria

Inclusion criteria

- A minimum of 6 months post-lesion/post-stroke to ensure that the subject 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 (ROM) 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. triceps surae with BoNT-A for spasticity reduction

Exclusion criteria

- Have a MAS score of 4

- Receive BoNT-A combined with other therapies aimed at reducing spasticity

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-08-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
After publication of the study the deidentified individual clinical trial participant-level data will be made available on the 4TU Research Data Repository..

Ethics review

Positive opinion

Date:	22-06-2021
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	NL9544
Other	METC VUmc : 2019.608 - NL71757.029.19

Study results