

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

Gepubliceerd: 22-06-2021 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26235

Bron

NTR

Verkorte titel

Reflexioning

Aandoening

Spinal Cord Injury and Stroke

Ondersteuning

Primaire sponsor: Sint Maartenskliniek Research

Overige ondersteuning: NWO Toegepaste en Technische Wetenschappen (TTW)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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 and 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.

Doel van het onderzoek

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

Onderzoeksopzet

T0: Prior to the botox injections

T1: 6 weeks after the botox injections

T2: 12 weeks after the botox injections

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Have a MAS score of 4

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	07-08-2020
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

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

Ethische beoordeling

Positief advies	
Datum:	22-06-2021
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	NL9544
Ander register	METC VUmc : 2019.608 - NL71757.029.19

Resultaten