Effect of intrathecal baclofen (ITB) therapy in ambulatory patients with generalized spasticity

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It is hypothesized that patients will improve their gait performance overtime and an exponential curve is expected between baclofen dose and daily walking activity.

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

Samenvatting

ID

NL-OMON27247

Bron
Nationaal Trial Register

Verkorte titel
ITB therapy

Aandoening

Patients with central neurological suffering and generalized spasticity during walking.

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

For the effect of ITB therapy on walking performance the main parameter is the covered

distance (meters) in the two minute walking test (2MWT).
For the dose-response relationship between the baclofen dose and daily walking activity the main parameter is the dose-response relationship between the baclofen dose and the 10 meter walking test (10mWT) score.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: The effect of interthecal baclofen (ITB) therapy on spasticity in central neurological disease (MS, CP, SCI, stroke) has been proven. However, literature on the effect on walking performance is scarce although there are indications that ITB therapy has a positive effect on patients' walking performance when spasticity in the legs is problematic. In clinical practice, clinicians are often reluctant to expose patients with walking function to ITB therapy because of the risk of losing walking function due to spasm reduction. So far, objective evaluation of the effect of ITB therapy on walking performance is insufficiently investigated. Therefore, we would like to investigate the effect of ITB therapy on walking performance in patients with central neurological diseases.
Objective: The aim of this study is to investigate effectiveness of ITB therapy on walking performance in patients with central neurological diseases and impaired walking due to spasticity. A secondary explorative aim is investigating the dose-response relationship between the baclofen dose and daily walking activity.
Study design: Prospective observational cohort study (No controls).
Study population: 12-15 patients with central neurological suffering (e.g. MS, CP, SCI, stroke); in chronic phase (>6 months) and generalized spasticity during walking; indication for ITB therapy with planned admittance to SMK; ≥16 years.Intervention: To objectively explore the effect of the ITB therapy patients will be asked to wear IMUs on both ankles during daytime of their inpatient admissions of the ITB trial pump (ITBext admission) and, if placed, the permanent ITB pump (ITBint admission). And during two physical therapy sessions; at baseline (preITB) and at twelve months follow-up (ITBfollow-up).
Main study parameters/endpoints: Primary outcome is the covered distance (meters) during the 2 minute walking test (2MWT). Secondary outcomes are spatiotemporal gait parameters, 10mWT, TUG, MAS, GAS, and BRPE & VAS scores regarding pain sensation, ease of walking and the hindrance from spasm during the 2MWT. Primary outcome for the dose-response relationship is the 10mWT score. Secondary outcomes are the MAS, gait parameters and VAS score regarding ease of walking during the 10mWT.

Doel van het onderzoek

It is hypothesized that patients will improve their gait performance overtime and an exponential curve is expected between baclofen dose and daily walking activity.

Onderzoeksopzet

This observational cohort study has four timepoints. preITB: The baseline measurement will take place one week before the ITB trial, during physical therapy. ITBext: the ITB trial measurement will take place around the 4th day after placement of the ITB trial pump, during physical therapy. ITBint: the ITB measurement (if permanent ITB pump is placed) will take place around the 4th day after placement of the permanent ITB pump, during physical therapy. ITBfollow-up: The follow-up measurement (if permanent ITB pump is placed) will take place approximately 12 months after placement of the permanent ITB pump. During inpatient rehabilitation the participant will be monitored (ITBext admission and ITBint admission). All timepoints are part of usual care.

Onderzoeksproduct en/of interventie

To objectively explore the effect of the ITB therapy patients will be asked to wear IMUs on both ankles during daytime of their inpatient admissions of the ITB trial pump (ITBext admission) and, if placed, the permanent ITB pump (ITBint admission). And during two physical therapy sessions; at baseline (preITB) and at twelve months follow-up (ITBfollow-up).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

I) Patients with neurological suffering (e.g. MS, CP, SCI, stroke). II) In chronic phase (>6 months). III) Generalized spasticity during walking (determined by instrumental gait analysis).

IV) Indication for ITB therapy with planned admittance to SMK. V) ≥16 years. VI) The use of walking aids is permitted.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Unable to grant permission for participation in the study (due to language issues or cognitive impairment).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-08-2019
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-12-2020
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	NL9150
Ander register	METC Arnhem Nijmegen : 2019-5483

Resultaten