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

No registrations found.

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

Summary

ID

NL-OMON27247

Source
Nationaal Trial Register

Brief title
ITB therapy

Health condition

Patients with central neurological suffering and generalized spasticity during walking.

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary study parameters for the effect of ITB therapy on walking performance; I) Spatiotemporal gait parameters measured by IMUs to identify an effect in gait pattern (walking velocity, stride length, number of steps, cadence, average stride length). II) 10mWT score, time (seconds) to cover 10 meters. During normal and dual-task condition. III) TUG score, time (seconds) to stand up, walk 3 meters, turn, go back and sit down. IV) Modified Ashworth scale (MAS) to assess spasticity. V) Goal attainment scale (GAS) to identify if goals set were reached. VI) Borg rating of perceived exertion (BRPE) scale (6-20 scale) to grade the experienced intensity/physical load during the 2MWT. VII) Visual Analoge Scale (VAS) regarding pain sensation, ease of walking and the hindrance from spasm experienced during the 2MWT.

Secondary study parameters for the dose-response relationship between baclofen dose and daily walking activity: I) Dose-response relationship between baclofen dose and other spatiotemporal gait parameters (number of walking periods, number of steps, walking duration, cadence, average step length). II) Dose-response relationship between baclofen dose and MAS. III) Dose-response relationship between baclofen dose and VAS score

Study description

Background summary

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.

Study objective

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

Study design

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.

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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

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):	19-08-2019
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-12-2020
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	NL9150
Other	METC Arnhem Nijmegen : 2019-5483

Study results