Pulmonary function and sleep related disorders during cervical admission of intrathecal baclofen in spinal cord injury; a safety study

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This study has been transitioned to CTIS with ID 2023-508143-51-01 check the CTIS register for the current data. Objective: The primary aim of the study is to demonstrate that cervical administered ITB is a safe treatment of spasticity of the UE...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON55571

Source
ToetsingOnline

Brief title
Safety of cervical intrathecal baclofen

Condition

- Spinal cord and nerve root disorders

Synonym
spinal cord injury and myelopathie

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

Source(s) of monetary or material Support: Medtronic,Neuro-bionic-foundation. Eigen financiering revalidatiecentrum (Roessingh;centrum voor revalidatie

Intervention

Keyword: intrathecale baclofen, sleep related disorders and pulmonary function, spasticity, upper extremities

Outcome measures

Primary outcome

Primary Objective:

The primary goal of the study is to demonstrate that cervical admission of ITB

is a safe treatment without deterioration of pulmonary and respiratory function

and possible increased risk or increased severity of SAS.

pulmonary function is mapped by means of spirometry. The quality of the

respiration is determined by capillary blood gas. Sleep-related breathing

disorders are measured by pulse-oximetry and polysomnography.

Secondary outcome

Secondary objective:

Secondary goal of the research is to explore the effect of cervical admission

of ITB on reduction of spasticity (both functional en satisfaction) and

improvement at the level of patients functions and activities.

Spasticity: This is measured by Perceived Resistance to Passive Movement (PRPM).

Patient satisfaction: This is measured by Patient Global Impression of Change

(PGIC).

The following parameters are already usual care before, during and after ITB

trial phase in Roessingh:

Function level:

• Muscle strength core muscles UE and LE by MRC scale.

• Passive range of motion (ROM) UE and LE in degrees

Activity/participation level

• COPM

• Time up and go test

• 10 meter walking test

We will add to this usual care for current study:

Function level:

• Force lateral and cylinder grasp

Activity/participation level:

• GRASPP

• QIF-sf

pulmonary function is mapped by means of spirometry. The quality of the

respiration is determined by capillary blood gas. Sleep-related breathing

disorders are measured by pulse-oximetry and polysomnography

Study description

Background summary

Intrathecal baclofen (ITB) is a proven effective treatment of spasticity. The effectiveness and safety of ITB treatment for lower extremity (LE) spasticity is well established. Much less is known about effectiveness and safety for the treatment of upper extremity (UE) spasticity. The concentration of baclofen in the spinal fluid decreases with increasing distance from the catheter tip. In theory to obtain an effect of ITB on spasticity of the UE the catheter tip

should be placed at cervical level.
However baclofen affects muscle tone, which may lead to a deterioration of pulmonary function and respiration and to an increase in sleep-related breathing disorders when administered cervical. In addition, however, reducing spasticity of respiratory muscles could improve breathing and lung function, and there would be no relationship with the development or worsening of sleep-related disorders.
The scarce literature does not show congruent results. Our hypothesis is that cervical ITB leads to reduction of spasticity and improvement of patient function and satisfaction without adverse effect on pulmonary and respiratory function and sleep-related breathing disorders.

Study objective

This study has been transitioned to CTIS with ID 2023-508143-51-01 check the CTIS register for the current data.

Objective: The primary aim of the study is to demonstrate that cervical administered ITB is a safe treatment of spasticity of the UE without deterioration of pulmonary function, respiration and sleep-related breathing disorders.

Study design

This is a prospective intervention study.

Intervention

An intrathecal catheter is placed just below spinal cord injury level. This is coupled to an extracorporal pump with baclofen. We will start with a dosage of 24 microgram/day. Depending on the effect, this is increased to a maximum of 200 micrograms per day.
If there is a possitive trial there is an indication for defenitive ITB treatment

Study burden and risks

During the trial, there are the already known possible complications as seen with the current ITB treatment. This concerns post-punctional headache, meningitis and other infections. Given the possible effect on lung function, respiration and sleep-related respiratory events, the trial will take place under close observation in the MST in Enschede. All these effects are reversible when the treatment is stopped. When there is a positive trial the patient can benefit from a definitive treatment with ITB.

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

Cervical spinal cord injury
Spasticity of upper extremities

Exclusion criteria

• Pregnancy
• Women of child bearing potential
• Nursing women
• Allergy baclofen
• Contra indication ITB (increased bleeding tendency, increased intracranial pressure, severe pressure ulcer)

• Oral anticoagulants
• Severe depression
• excessive alcohol use
• Patients depending on ventilation
• Not adequately treated SAS
• PcCO2 > 6,5 KPa

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2023
Enrollment:	11
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Baclofen Sintetica Intrathecaal
Generic name:	Baclofen Sintetica Intrathecaal
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	03-02-2022
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EU-CTR	CTIS2023-508143-51-01
EudraCT	EUCTR2021-004994-30-NL
CCMO	NL68837.091.21