Electromyography to assess the change in muscle activity as a result of intrathecal baclofen treatment

Published: 20-10-2023
Last updated: 16-11-2024

Electromyography to assess change in muscle activity as a result of intrathecal baclofen treatment

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53254

Source
ToetsingOnline

Brief title
EMG in ITB

Condition

- Neuromuscular disorders

Synonym
spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electromyography, Intrathecal baclofen, Modified Ashworth Scale, Spasticity

Outcome measures

Primary outcome

The main study endpoint is the change in muscle activity measured by EMG. The change in muscle activity is assessed by analysis of the amplitude, the root mean square, the power spectral density and the co-contraction index of the EMG signals. The EMG signals are measured during rest, during the MAS assessment and during voluntary contraction by the participant.

Secondary outcome

Secondary study parameters are the MAS indices of the participants before and after ITB treatment and the Patient Global Impression of Change reported by the participants, and the correlation between de EMG features and MAS and PGIC.

Study description

Background summary

Baclofen is a muscle relaxant drug that is used in the treatment of spasticity. The dose of baclofen must be set accurately, else the patient will either have no treatment of the baclofen or will lose the functionality of the healthy muscles that still respond. Side effects of oral baclofen include drowsiness and sedation, nausea, hypotension, dizziness, headaches and more. Intrathecal delivery of baclofen can be a possible alternative for patients presenting with severe side effects or little therapeutical benefit of oral baclofen. When using intrathecal baclofen delivery, an implanted pump with a refillable reservoir delivers low dosages of baclofen through a catheter into the intrathecal space throughout the day. The local delivery of baclofen increases the concentration levels at the target and decreases the chance of (systemic) side effects. Patients possibly benefiting from intrathecal baclofen (ITB) must pass an initial trial, before a permanent ITB system can be implanted.

Effects of oral baclofen and ITB are established using the Modified Ashworth Scale (MAS), which grades muscle tone by moving limbs while assessing resistance to the movement, and patient experience. Both these methods are limited in reliability and are poorly correlated. Ideally, the effect of the administered dose of ITB would be assessed using a more objective method. Electromyography (EMG) is a promising tool for objective monitoring of the effect of ITB on muscle activity.

Study objective

Electromyography to assess change in muscle activity as a result of intrathecal baclofen treatment

Study design

This study is a mono-centre, prospective, explorative study

Study burden and risks

The participants receive standard care. The only addition is the measurement of muscle activity using EMG during the MAS assessment. EMG measurement is a non-invasive measurement with negligible risk. MAS assessment is part of the standard procedures. The equipment, software and sensors used in this study are tested for neurophysiological measurements and part of standard care.
The participants participating in this research will not be exposed to any significant risks as a result of the research. This study can only be done using this patient group.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Receiving an intrathecal baclofen trial (single shot baclofen test or external intrathecal baclofen pump implantation) or permanent intrathecal baclofen pump implantation
• Unilateral or bilateral spasticity of lower limbs
• Modified Ashworth Scale and electromyography measurements possible (18,5 * BMI < 30)
• Able to understand and comply to verbal instructions

Exclusion criteria

• Age under 18 years old
• High sensitivity of lower limb skin

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2023
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	20-10-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL83951.078.23