Optimal inter stimulus interval in spinal mTc-MEP monitoring. A multicenter study.

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The aim of this research proposal is to examine the effect of different ISIs on mTc-MEPs.Primary research question: What is the effect of different interstimulus intervals (ISIs) on mTc-MEP thresholds, peak-to-peak amplitudes, and area under the...

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

Summary

ID

NL-OMON53760

Source
ToetsingOnline

Brief title
Optimal inter stimulus interval in mTc-MEP monitoring

Condition

- Spinal cord and nerve root disorders

Synonym
for example scoliosis surgery., Surgeries with a risk of damage to the spinal cord

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ISI, Motor evoked potential, Stimulation parameters, Transcranial electrical stimulation

Outcome measures

Primary outcome

The main study parameters are mTc-MEP motor thresholds, amplitudes, and AUC of

the tibialis anterior (TA) and abductor hallucis (AH) muscles, associated with

different ISI stimulations (1, 2, 3 and 4 ms).

Secondary outcome

1. Variability will be based on peak-to-peak amplitudes

2. Optimal ISI for the 2 different stimulators will be determined based on the

primary outcome variables.

3. Time and amplitudes will be used to answer this research question.

Study description

Background summary

Intraoperative neurophysiological monitoring (IONM) is used to detect and prevent neurological damage during surgeries with a high risk of neurological damage. Muscle transcranial electrical stimulation motor evoked potential (mTc-MEP) monitoring is an IONM modality that is commonly used during spinal surgery. Stimulation parameters, such as the interstimulus interval (ISI), influence the characteristics of mTc-MEPs. The aim of this research proposal is to examine the effect of different ISIs on mTc-MEPs. Optimal ISI is defined as the ISI that can generate MEPs with the lowest motor thresholds or the highest peak-to-peak amplitudes.

Study objective

The aim of this research proposal is to examine the effect of different ISIs on mTc-MEPs.

Primary research question:
What is the effect of different interstimulus intervals (ISIs) on mTc-MEP thresholds, peak-to-peak amplitudes, and area under the curve (AUC)?

Secondary research questions:
1. What is the influence of different ISIs on the variability of mTc-MEP amplitudes and thresholds?
2. Is the optimal ISI different for constant current (LMU hospital Munich) and constant voltage (UMCG) stimulators?
3. Does the optimal ISI shift over time?

Study design

Prospective observational study.

Study burden and risks

The total anesthesia time will be extended by maximal 20 minutes per patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The patient will undergo a surgery with spinal mTc-MEP monitoring

Exclusion criteria

The patient had pre-existing muscle weakness in the AH or TA muscles

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-12-2023
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	08-06-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL82612.042.22