Measuring the electromyographic (EMC) muscle response

No registrations found.

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

Summary

ID

NL-OMON23335

Source
NTR

Brief title
NEAT

Health condition

patients receiving neuromuscular blocking agents required for their clinical care during a surgical procedure

Sponsors and support

Primary sponsor: university medical center groningen
Source(s) of monetary or material Support: no funding

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to provide EMG performance data of the TetraGraph device on anesthetized subjects. Performance will be assessed post hoc by analyzing objective EMG data and correlating with the responses to annotations made during the surgical procedure (e.g., correlating the EMG responses to the time of NMBA administration).

Secondary outcome

o Investigating the quality of the applied skin electrodes (clinically available 3M Red Dot electrodes)

o Observing the applicability of the prototype (easy of use, ...)

Study description

Background summary

Incomplete recovery from neuromuscular blockade after anesthesia and surgery continues to be a common problem in the post-anesthesia care unit. There is an urgent need for an easy-to-use and accurate quantitative neuromuscular monitor in the clinical setting using neurostimulation

Study objective

There is an urgent need for an easy-to-use and accurate quantitative neuromuscular monitor in the clinical setting

Study design

During operation

Intervention

As this is an observational trial, no additional interventions will be done.

Contacts

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Eligibility criteria

Inclusion criteria

- Age 18 years or older;

- Subject meets the American Society of Anesthesiology (ASA) physical status I-III criteria (Table I);

- Subject has provided written informed consent.

Exclusion criteria

- Presence of an underlying neuromuscular disease

- Presence of renal or hepatic disease

- Subject has open skin sores at locations needed for electrode application

- Patient taking the following medication:

- anti-seizure medication

- anti-cholinestase medication

- magnesium sulfate

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):	10-09-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-09-2014
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	NL4626
NTR-old	NTR4777
Other	: 2014/218

Study results