Improving the accuracy of determination of onset of neuromuscular block

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

Summary

ID

NL-OMON32338

Source
ToetsingOnline

Brief title
A closer look at onset of neuromuscular block

Condition

- Neuromuscular disorders

Synonym
muscle disease

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: Muscle relaxation

Outcome measures

Primary outcome

The main study parameters are the prediction accuracy of a PK-PD-potentiation model fitted with a Bayesian procedure to the twitch response data gathered at the adductor pollicis (thumb) from 1 Hz ST neuromuscular stimulation. Bayesian prior values for PK model parameters will be obtained from relevant literature.

Secondary outcome

The secondary study parameters are the onset profile of (modeled) neuromuscular block predicted by the fitted PK-PD-potentiation model.

Study description

Background summary

The speed of onset of muscle relaxation is an intrinsic property of neuromuscular blocking agents (NMBA). It is an important factor in choosing the appropriate NMBA for certain clinical conditions, especially when a rapid onset of action is desired. Physiological process such as perfusion, blood-mixing, receptor affinity and protein binding are thought to play a role in determining the speed of onset of NMBA drug effect, however the nature of the influence of these mechanisms on the observed onset of muscle relaxation is not well understood. The design of new NMBAs and drug application methods would also benefit from a better understanding of the physiological mechanisms of drug onset.

If we wish to study the effect of rapid onset NMBAs we must obtain a number of neuromuscular monitoring measurements observations during the development of onset of neuromuscular block. Standard clinical neuromuscular monitoring practice is insufficient to study rapid drug onset because it utilizes low-frequency repetitive stimulation patterns, typically 0.1 Hz single twitch

(ST) or 0.067 Hz train-of-four (TOF) to determine muscle strength and estimate the degree of neuromuscular block. With these low-frequency stimulation patterns, stimulation intervals are long enough for twitch strength to change significantly between stimulations. In the case of a rapid onset of drug effect, only very limited number of twitches can be observed during onset. It follows that the information content of the twitch responses during onset is limited and estimations of speed of onset of muscle relaxation must have considerable uncertainty. In short, our ability to study the time course of muscle relaxation, especially during rapid onset, is limited by the stimulation frequency of neuromuscular monitoring.

Neuromuscular monitoring using medium-frequency stimulation pattern, for example 1 Hz ST, provides considerably more twitch response information that standard neuromuscular monitoring practice because the stimulus internal is smaller. This potentially allows more certain and accurate observation of drug effect onset.

Study objective

The primary objective of the study is to determine if twitch response following rocuronium administration evoked by 1 Hz ST neuromuscular monitoring can be modeled to a similar degree of accuracy as previously published studies describe for 0.1 Hz (ST) or 0.067 Hz (TOF) stimulation frequency, a prediction accuracy of about 2%-5% of baseline response. The secondary objective is to determine if estimated rocuronium onset characteristics during 1 Hz ST neuromuscular monitoring are significantly different than previously published data.

Study design

The study will be an observational study of clinical patient twitch response data.

Study burden and risks

Patients are likely to receive intermittent neuromuscular stimulation as a part of standard neuromuscular monitoring. The devices used for the study will be standard clinical neuromuscular monitoring devices (TOF- Watch SX), registered for routine clinical use. Patients will be under general anesthesia during the entire period of neuromuscular monitoring and will experience no physical or psychological discomfort from the study. The risks associated with 1 Hz neuromuscular stimulation are widely thought to be nihil, this method has been applied in other studies of neuromuscular function. The subject will receive no benefit from taking part in the study.

No blood samples will be taken, no patient questionnaires or diaries will be

collected, and no physical examinations or site visits will take place. During the course of the investigation no information relevant to individual patient treatment will become available as a result of the performance of the study.

The study results concern patients undergoing surgical procedures and should therefore be performed on such patients. The study will not be performed on minors or incapacitated persons.

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

- General anaesthesia for two hours or more
- ASA class I or II
- Administration of rocuronium for intubation only

• Administration of propofol for anaesthesia induction and maintenance
• Operation allows neuromuscular monitoring using the TOF-Watch at the adductor pollicis muscle
• Age 18-70 years
• BMI < 30

Exclusion criteria

• Administration of drugs interfering with neuromuscular block or monitoring
• Neuromuscular disease
• Diabetes mellitus type I or II
• Allergy to rocuronium
• Allergy to propofol
• Conditions interfering with neuromuscular monitoring using the TOF-Watch

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2009
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

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	NL22573.042.08