Comparison of the TOF-Cuff NMT Monitor to the TOF-Watch SX acceleromyograph for perioperative neuromuscular monitoring.

No registrations found.

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

Summary

ID

NL-OMON25935

Source
NTR

Health condition

neuromuscular monitoring, TOF-Cuff, TOF-Watch

Sponsors and support

Primary sponsor: Radboudumc, Nijmegen, The Netherlands
Source(s) of monetary or material Support: Radboudumc, Nijmegen, The Netherlands

Intervention

Outcome measures

Primary outcome

the bias and limits of agreement of the TOF-Cuff NMT Monitor and the TOF-Watch SX acceleromyograph for perioperative neuromuscular monitoring

Secondary outcome

the bias and limits of agreement of the TOF-Cuff NMT Monitor and the TOF-Watch SX acceleromyograph for perioperative neuromuscular monitoring?

Study description

Study objective

The TOF Cuff NMT monitor is as reliable as the TOF-Watch SX acceleromyograph for perioperative neuromuscular monitoring.

Study design

Time to onset of neuromuscular block is measured for both devices. Onset is defined as time from start of injection until 95% depression of T1. After this paired measurements are taken in all phases of neuromuscular block : the profound/deep phase, in the moderate phase and in the recovery phase. When, during the recovery/progression of the neuromuscular block, the TOF-watch shows a measurement in the range of the next study-measurement the corresponding TOF-cuff value is noted (see table 1.). Because both devices will measure every 30 seconds the maximal time between two measurements of both devices is 15 seconds. In each predefined range of neuromuscular relaxation 3 measurements will be taken to correct for slight variations of the measurements in each device.

Intervention

Perioperative neuromuscular monitoring with both the TOF-Cuff NMT Monitor and the TOF-Watch SX acceleromyograph.

Contacts

Public
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Eligibility criteria

Inclusion criteria

15 patients, age >18 years, American Society of Anesthesiologists physical status I-III, undergoing elective surgery in supine position with both arms abducted, under general anesthesia with orotracheal intubation aided by administration of a non-depolarizing neuromuscular blocking agent.

Exclusion criteria

- No informed consent

- Neuromuscular disease.

- Diabetes Mellitus

- Indication for rapid sequence induction

- Expected difficult intubation or ventilation

- Pregnancy

- Allergy to neuromuscular blocking agent (rocuronium)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2018
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion Date:	24-12-2017
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	NL6735
NTR-old	NTR6913
Other	CMO-code : 2017-3858

Study results