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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25935

Bron
NTR

Aandoening

neuromuscular monitoring, TOF-Cuff, TOF-Watch

Ondersteuning

Primaire sponsor: Radboudumc, Nijmegen, The Netherlands
Overige ondersteuning: Radboudumc, Nijmegen, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No informed consent

- Neuromuscular disease.

- Diabetes Mellitus

- Indication for rapid sequence induction

- Expected difficult intubation or ventilation

- Pregnancy

- Allergy to neuromuscular blocking agent (rocuronium)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018

Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6735
NTR-old	NTR6913
Ander register	CMO-code : 2017-3858

Resultaten