

To Cuff Study

No registrations found.

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

Summary

ID

NL-OMON24381

Source

Nationaal Trial Register

Brief title

ToCuff

Health condition

N.A.

Sponsors and support

Primary sponsor: LUMC

Source(s) of monetary or material Support: MSD

Intervention

Outcome measures

Primary outcome

TOF and TOF ratio values differences between both groups

Secondary outcome

Time to TOF Ratio 0.9

Study description

Background summary

This is an observational, non-inferiority trial in which we will compare the TOF cuff device to electromyography (EMG). All patients will receive general anesthesia (with rocuronium). Patients will have the TOF cuff and EMG placed on the same or extremity (hand for EMG, upper arm for TOF cuff). Measurements will be done during the entire procedure. We will perform a pilot study with 250 patients to ensure that reliable estimates of repeatability coefficient, bias, and limits of agreement are obtained.

Study objective

The TOF cuff behaves similarly to EMG in terms of bias, limits of agreement and precision when comparing the TOF cuff to EMG.

Study design

N.A.

Intervention

N.A.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- (i) ASA class I-III
- (ii) > 18 years of age;
- (iii) Ability to give oral and written informed consent.

Exclusion criteria

- (i) Known or suspected neuromuscular disorders impairing neuromuscular function;
- (ii) Allergies to muscle relaxants, anesthetics or narcotics;
- (iii) A (family) history of malignant hyperthermia;
- (iv) Women who are or may be pregnant or are currently breast feeding;
- (v) Renal insufficiency, as defined by a glomerular filtration rate < 30 ml/min
- (vi) Scheduled for anesthesia without the use of muscle relaxants.

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):	17-11-2017
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 28-06-2019

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	NL7837
Other	METC LUMC : P17.050

Study results