Evaluation of the TOF CUFF for perioperative neuromuscular transmission monitoring during recovery of moderate and deep neuromuscular block compared to acceleromyography and electromygraphy

Published: 06-04-2017
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To compare the bias, limits of agreement and precision of the TOF cuff relative to EMG during recovery of moderate and deep neuromuscular block in patients with normal body mass index and morbidly obese patients. All techniques are currently used at...

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

Summary

ID

NL-OMON48823

Source
ToetsingOnline

Brief title
To CUFF

Condition

- Other condition

Synonym
Anesthesia, Narcosis

Health condition

anesthesie

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Merck Sharp & Dohme (MSD)

Intervention

Keyword: anesthesia, monitoring, relaxation

Outcome measures

Primary outcome

The outcome of the monitor devies

Secondary outcome

None

Study description

Background summary

Neuromuscular monitoring is mandatory during anesthesia. Acceleromyography (AMG) is the most wide spread used method because it is easy to apply and accurate enough for daily practice. However AMG is known to be inaccurate when compared to the gold standard in neuromuscular transmission monitoring, electromyography (EMG). Furthermore when the patient*s arms require to be positioned next to the body and beneath surgical drapes, AMG measurements are often hindered and inaccurate. The TOF cuff is a device, which measures NMB at the upper arm with a blood pressure cuff. It overcomes the previously mentioned disadvantages of AMG. However, it validity compared to EMG has not yet fully been investigated.

Study objective

To compare the bias, limits of agreement and precision of the TOF cuff relative to EMG during recovery of moderate and deep neuromuscular block in patients

with normal body mass index and morbidly obese patients. All techniques are currently used at LUMC and all devices have CE marking for the intended use.

Study design

Observational, open design

Study burden and risks

None

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2017
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	06-04-2017
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	31-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	05-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	22-07-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60865.058.17

Study results

Date completed:	06-08-2020
Actual enrolment:	250