Effect of neuromuscular blockade reversal with sugammadex on oxygenation, pain and arousal states in the post-anesthesia care unit

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26051

Source
Nationaal Trial Register

Brief title
Neuropa

Health condition

Sugammadex, Train of four ratio, Respiration, Post operative

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: MSD

Intervention

Outcome measures

Primary outcome

Postoperative SpO2 level obtained at 2-min interval for 45 minutes and the need for

supplemental oxygen

Secondary outcome

Pain, respiratory rate, sedation and lowest TOF ratio

Study description

Background summary

Muscle relaxants are routinely used during general anesthesia. However, when at the end of surgery reversal is suboptimal, it's use is assiociated with an increase in postoperative complication, most importantly hypoxemia in the first 30-45minutes in the recovery room. Since 2008 an intense and rapid reversal of a rocuronium-induced neuromuscular block is possible with the use of sugammadex.

The current study is aimed at assessing the effect of sugammadex on the postoperative respiratory condition compared to the (traditionnally used) neostigmin. The patient will be randomized to receive sugammadex or neostigmin as reversal of the neuromuscular block and respiratory conditions will be monitored during the first 45minutes at the recovery room.

Study objective

We hypothesize that reversal with sugammadex leads to favorable postoperative respiratory conditions, less sedation and lower pain levels as compared to reversal with the (traditionally used) acetylcholinesterase inhibitor neostigmin

Study design

- Peroperative: bispectral index, TOF count, TOF ratio

- Postoperative: SpO2, respiratory rate, oxygen consumption, pain, sedation, occurence of nausea/vomiting, blood pressure, heart rate

Intervention

According to the randomization list the patient will receive at the end of the surgery sugammadex 2mg/kg or neostigmine 2.5 mg + atropine 1 mg at a NMB level of TOF>0

Contacts

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Eligibility criteria

Inclusion criteria

- Age >18 years

- Body mass index < 35 kg/m2

- ASA class I-III

- Patients scheduled for elective surgery requiring anesthesia with the use of neuromuscular blocking agents.

Exclusion criteria

- Known or suspected neuromuscular disorder impairing neuromuscular function

- Allergie to muscle relaxants, anesthesics or narcotics.

- A (family) history of malignant hyperthermia

- Women who are or may be pregnant or are currently breast feeding

- Contraindication for the use of neostigmine (intestinal obstruction, COPD GOLD 4 or abnormal heart rhythm)

- Surgery requiring neuraxial anesthesia/analgesia

- Preoperative cognitive dysfunction or mental disabilities

- Preexistent significant pulmonary disease with preoperative SpO2<90%

- Preoperative ICU treatment/intubation (ICU patient);

- Need for postoperative ICU treatment or ventilation

- Renal insufficiency (GFR<30 mL/min or oligura < 0.5 mg/kg/h)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-08-2015
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	NL5262
NTR-old	NTR5378
Other	Medisch Ethische Toetsingscommissie (METC) : P14.060

Study results