Effect of depth of neuromuscular block on intraoperative surgical conditions as determined by the Leiden Surgical Rating Scale in morbidly obese patients undergoing laparoscopic bariatric surgery

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- To assess whether the implementation of a deep neuromuscular block (NMB) (PTC 1-2) combined creates optimal surgical conditions as measured by the surgeon (using the 5-point Leiden surgical rating scale) versus a moderate neuromuscular block (TOF…

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

Summary

ID

NL-OMON44073

Source
ToetsingOnline

Brief title
BLISS 3

Condition

- Other condition

Synonym
perioperative surgical conditions

Health condition

obesitas

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Morbidly obese, neuromuscular blok, Surgery, surgical conditions

Outcome measures

Primary outcome

Surgical conditions, with as main research question *Does a deep surgical block indeed improve surgical conditions in case of laparoscopic surgery in morbidly obese patients for bariatric surgery?* The surgical condition will be determined from a surgical rating condition scale, the Leiden Surgical rating Scale. This is a 5-point ordinal scale ranging from 1 = poor condition to 5 = optimal surgical conditions. The surgeon will score the condition at 15 min intervals. At the time of scoring also the intra-abdominal pressure will be monitored.

Secondary outcome

Secondary end-points include:

(1) The hemodynamics during surgery with the main research question *Does a deep neuromuscular block coincide with improved hemodynamics during surgery and less postoperative pain?*

(2) Cardiorespiratory conditions in the post-anesthesia care unit, with the main research question *What is the effect of reversal with Sugammadex of a

deep surgical muscle block on postoperative breathing activity as measured by respiratory rate and saturation* (3) Pain and sedation in the post-anesthesia care unit, with the main research question *Does a deep block coincide with less pain compared to a moderate block in the recovery period?* and (4) The Postoperative Quality of Recovery Scale (PQRS), with the main question *Irrespective of depth of the neuromuscular block during surgery, is the quality of recovery similar in patients that were reversed with sugammadex*.

Study description

Background summary

In laparoscopic surgery, especially when surgery is performed in morbidly obese patients, surgical conditions are determined in a major if not exclusive part by the depth of the neuromuscular block. A deep block (PTC 1-2) is often associated with improved surgical conditions and is therefore requested by the surgeons. However, a deep block comes at the expense of a variety of items that may conflict with its use including long recovery times, postoperative ventilation and impaired postoperative breathing conditions with atelectasis and hypoxia. With the introduction of Sugammadex there is now the possibility to reverse an even deep surgical block. This may overcome most of the issues mentioned.

Previously we showed that a deep NMB coincided with favorable surgical conditions in lean patients undergoing elective laparoscopic retroperitoneal surgery for prostatectomy or nephrectomy (See Figure 1). During a moderate NMB 20% of surgical scorings were less than good, during deep NMB 99% of scorings were excellent. In the current study we will examine the effect of the depth of the neuromuscular block in morbidly obese patients on one major end-point:

To address these research questions, we will relax morbidly obese patients undergoing bariatric surgery with rocuronium. Patients will be randomly assigned to receive a moderate neuromuscular block (standard care) with a TOF of 1-2 or a deep NMB (deep block) with a TOF of zero and PTC of 1-2. Rocuronium will be administered as bolus infusion ranging from 0.6 - 1 mg/kg. Titration to effect will be performed immediately after intubation.

After surgery had ended patients that received standard care will be reversed with 2 mg/kg sugammadex, while patient that received the deep block will receive 4 mg/kg sugammadex. Extubation will be performed when the TOF ratio > 0.9 and the patients breathes adequately.

In the post-anesthesia care unit the cardiorespiratory parameters (blood pressure, heart rate oxygen saturation), the level of pain (on an 11-point numerical rating scale), sedation and the PRQS will be measured at 15 min intervals until discharge to the ward.

The results of the study will give the following valuable information:
1. Does the level of muscle relaxation affect surgical conditions when performing laparoscopic bariatric surgery?
2. Does a deep block lead to improved hemodynamic conditions during surgery?
3. What is the respiratory condition of the patients following a deep block?
4. Do patients after laparoscopic bariatric surgery experience less pain compared to patients with a moderate neuromuscular block?
5. Does reversal with sugammadex lead to similar quality of recovery despite dissimilar depths of neuromuscular block?
Finally, the current study will add to the existing database on the association between the depth of the neuromuscular block and the rating of surgical conditions. A meta-analysis will be performed on the current data set (BLISS 1-3) allowing confirmation of the association between a deep block and improved surgical conditions in over 160 patients undergoing complex laparoscopic surgery.

Study objective

- To assess whether the implementation of a deep neuromuscular block (NMB) (PTC 1-2) combined creates optimal surgical conditions as measured by the surgeon (using the 5-point Leiden surgical rating scale) versus a moderate neuromuscular block (TOF 1-2) in morbidly obese patients undergoing bariatric surgery.
-To assess whether reversal of the deep NMB with sugammadex 4 mg/kg results in optimal cardiorespiratory conditions in the post-anesthesia care unit.

Hypotheses
-Deep NMB combined will result in a significant improvement of surgical conditions compared to moderate NMB;
-Reversal of deep NMB with sugammadex results in optimal cardiorespiratory conditions in the postanesthesia care unit.

Study design

This is a randomized control trial (RCT) performed

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

ASA 1-3,
18 years or older;
BMI > 34 kg/m2;
ability to give informed consent; elective bariatric surgery.

Exclusion criteria

Known or suspected neuromuscular disorders impairing neuromuscular function; allergies to muscle relaxants, anesthetics or narcotics;
A (family) history of malignant hyperthermia;
Women who are or may be pregnant or are currently breast feeding;
Renal insufficiency

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-02-2016
Application type:	Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL52829.058.15