The effect of the depth of neuromuscular block and pneumoperitoneum on postoperative pain after a gastric bypass

No registrations found.

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

Summary

ID

NL-OMON26521

Source
NTR

Brief title
Bar Press Trial

Health condition

EN: Morbid obesity, bariatric surgery, gastric bypass, postoperative pain, pneumoperitoneum, deep neuromuscular block
NL: Morbide obesitas, bariatrische chirurgie, gastric bypass, postoperatieve pijn, pneunoperitoneum, diepe neuromusculaire block.

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The primary outcome of the pilot study is to determine which of the 4 groups are feasible to include in the actual trial. A cut off point of conversion from one of the treatment arms of more than 40% of the patients has been set to determine if that treatment arm is feasible to include in the trial.

Secondary outcome

Secondary outcome measures are postoperative pain.

Study description

Background summary

Aim of this pilot study is to determine which intervention groups are feasible in a larger trial which aims to compare postoperative pain and complication rates in moderate versus deep neuromuscular blockade, and normal versus low intra-abdominal pressure, in a double-blinded, randomized controlled pilot study. We will be comparing 4 groups of 15 patients, undergoing laparoscopic bariatric surgery with deep neuromuscular block versus normal neuromuscular block and normal-pressure pneumoperitoneum versus low-pressure pneumoperitoneum in a 2x2 table design. Patient and surgeon are blinded. The anesthesiologist is not blinded in order to control the depth of the neuromuscular block and pressure. The study will be performed in a large secondary hospital (Franciscus Gasthuis & Vlietland, Rotterdam area, the Netherlands). Obese patients found suitable for bariatric surgery according to the current guidelines, undergoing a primary gastric bypass, will be included in the study. Patients unwilling to give informed consent or with allergies for used medication, neuromuscular comorbidities or a medical history of pain disorders will be excluded. Patients will receive either deep neuromuscular block, measured with post-tetanic count (PTC), or moderate neuromuscular block, measured with Train-of-Four (TOF). They will be operated under either normal pressure pneumoperitoneum (20 mmHg in our centre) or low pressure pneumoperitoneum (12 mmHg). In case of unacceptable surgical conditions, either neuromuscular block or pneumoperitoneum or both will be increased, depending on the group for which the patient has been randomised. The primary endpoint is quality of the surgical field (Graded on the Leiden Surgical Rating Scale), to be scored directly after sign out procedure. Secondary endpoints are post-operative pain, the influence of pain on readiness for discharge and length of hospital stay, and complications during surgery or within 1 month postoperatively; i.a. bleeding, leakage.

Study objective

When using deep neuromuscular blockade, less intraabdominal pressure will be needed for good surgical overview, which will lead to a decrease in postoperative pain.

Study design

During surgery (overview), day 1-7 for postoperative pain scores.

Intervention

Patients will receive either deep or moderate neuromuscular blockade and either standard or low pressure pneumoperitoneum.

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Eligibility criteria

Inclusion criteria

Primary bariatric procedure; good command of the Dutch language.

Exclusion criteria

Allergies for used medication, neuromuscular comorbidities, a medical history of pain disorders such as ACNES, fibromyalgia or CRPS, insufficient command of the Dutch language or unwillingness to supply informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44329
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7050
NTR-old	NTR7255
CCMO	NL64025.101.17
OMON	NL-OMON44329

Study results