PILOT STUDY PROTOCOL: LOW-PRESSURE PNEUMOPERITONEUM WITH DEEP NEUROMUSCULAR BLOCKADE IN BARIATRIC SURGERY TO REDUCE POSTOPERATIVE PAIN

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON44329

Source
ToetsingOnline

Brief title
Bar-press trial

Condition

- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
(Morbid) obesity, extreme overweight

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Stichting

Intervention

Keyword: Bariatric surgery, Gastric bypass, Low-pressure pneumoperitoneum, Neuromuscular blockade

Outcome measures

Primary outcome

1. Quality of surgical field (Graded on the Leiden Surgical Rating Scale), to

be scored directly after sign out procedure. 2. Postoperative pain;

questionnaire until 7 days postoperatively, length of hospital stay, usage of

analgesia.

Secondary outcome

Complications during surgery or within 1 month postoperatively; i.a. bleeding,

leakage.

Study description

Background summary

Laparoscopy is the golden standard in bariatric surgery. General guidelines of laparoscopy recommend to operate using the minimum intra-abdominal pressure needed for a good overview. For the obese, higher pressures are often used to create a surgical field of sufficient quality. However, studies have shown that decreased intraabdominal pressure might reduce postoperative pain. Therefore it would be desirable to operate with a low-pressure, maintaining a good quality of surgical field and without increasing the number of adverse events. Up until now, there is no consensus which combinations of pressure and block type are optimal in obese patients.

Study objective

Aim of this pilot study is to determine which intervention groups are feasible in a larger trial which aims to a compare postoperative pain and complication rates in moderate versus deep neuromuscular blockade, and normal versus low intra-abdominal pressure.

Study design

This is a double-blinded, randomized controlled pilot study, to test feasibility of a planned trial. 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. 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).

Intervention

Patients will receive either deep neuromuscular block or moderate neuromuscular block, measured with PTC. They will be operated under either normal pressure pneumoperitoneum (20 mmHg in our centre) versus low pressure pneumoperitoneum (12 mmHg). In case of unacceptable surgical conditions, either neuromuscular block or pneumoperitoneum will be increased, depending on the group in which the patient is randomised.

Study burden and risks

Patients will be asked to keep a pain diary during the first week after surgery and will receive an extra phone call from the investigator to inform on their wellbeing on day 3. The risk of the investigational treatment is possible longer duration of surgery due to less overview. Benefit is the expected lower pain score after surgery. We conclude that the benefits of the interventions outweigh the minor risks.

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

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, or no informed consent.

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26521
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64025.101.17
OMON	NL-OMON26521