

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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26521

Bron

Nationaal Trial Register

Verkorte titel

Bar Press Trial

Aandoening

EN: Morbid obesity, bariatric surgery, gastric bypass, postoperative pain, pneumoperitoneum, deep neuromuscular block

NL: Morbide obesitas, bariatrische chirurgie, gastric bypass, postoperatieve pijn, pneumoperitoneum, diepe neuromusculaire block.

Ondersteuning

Primaire sponsor: Franciscus Gasthuis & Vlietland

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Primary bariatric procedure; good command of the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	28-05-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44329
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten