The impact of neuromuscular relaxation and nociception guided anaesthesia on hemodynamic variables during abdominal laparoscopic surgery: a strategy trial.

Published: 07-08-2019
Last updated: 09-04-2024

to study the effect of depth of neuromuscular block and nociception level guidance on hemodynamic variables during abdominal laparoscopic surgery

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52953

Source
ToetsingOnline

Brief title
RELAX-LAP

Condition

- Other condition

Synonym
anesthesia

Health condition

anesthesie, laparoscopie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anaesthesia, cardiac function, nociceptie, relaxation

Outcome measures

Primary outcome

Mean arterial pressure at 30 minutes after installation of the pneumoperitoneum

Secondary outcome

Mean arterial pressure at all other time points

Left ventricular ejection fraction, stroke volume, systolic and diastolic

function, afterload and cardiac output

Stroke volume variation

Systemic vascular resistance

Haemodynamic instability score

Study description

Background summary

Many surgical procedures are performed using the laparoscopic approach. However, insufflation of the abdomen (pneumoperitoneum) has detrimental hemodynamic effects. The magnitude of haemodynamic changes after pneumoperitoneum depend on several major variables: (1) insufflation pressure; (2) patient position; (3) depth of anesthesia (4) nociception-antinociception balance and (5) the level of neuromuscular block (NMB). Some of these variables have been studied in the past, however new developments within the field of

anaesthesia now enable anaesthesiologists to apply deep neuromuscular blockade and to balance nociception-antinociception during surgery. The effect of these techniques on haemodynamic control during pneumoperitoneum are however not well established. We will perform an experimental strategy study to evaluate the effect of a goal directed anaesthesia strategy with deep NMB (PTC 1-2) and nociception guided anesthesia regimen using the Nociception Level Index (NOL) on relevant hemodynamic parameters during abdominal laparoscopic surgery.

Study objective

to study the effect of depth of neuromuscular block and nociception level guidance on hemodynamic variables during abdominal laparoscopic surgery

Study design

prospective, randomized controlled strategy trial

Intervention

Patients in this group will receive deep NMB, aimed at PTC 1-2 during the entire procedure. The NMB will be maintained with a continuous infusion of rocuronium and reversed at the end with sugammadex. In addition, opioid dosing will be guided using the nociception level index.

Study burden and risks

Patients will receive an arterial cannula in the radial artery for beat to beat recordings of their hemodynamic variables. In addition, transesophageal echocardiography will be performed. Both measurements give valuable information of the patient*s hemodynamics and are commonly used in our department; they are associated with a low risk of complications. In addition, because these techniques are applied after patients are a sleep and removed before awakening, there is no direct discomfort. Deep neuromuscular block, single shot neuromuscular block and nociception monitoring are all standard of care at the LUMC.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

ASA 1-3
Age > 18
Scheduled for laparoscopic or robotic abdominal surgery
Ability to give oral and written consent

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;
Preexisting cardiac disease (any);
Untreated or uncontrolled hypertension;
COPD gold 3 or higher
Any contradictions for TEE:
Preexistent esophageal pathology (stricture, tumor, diverticulum)
Any increased risk factor for upper gastro intestinal tract bleed:
History of GI surgery;
History of GI bleed;
Esophageal varices;
Gastric or esophageal inflammation;

Severe thrombocytopenia (less than 50k) or severely elevated INR (>4).

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-12-2020
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	07-08-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-02-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
Other	het protocol wordt geregistreerd op clinicaltrials.gov
CCMO	NL69290.058.19