Sevoflurane/fentanyl anesthesia guided by Nociceptive-Level index during abdominal surgery in ASA 1-3 patients – a randomized controlled trial on the effect of NOL-guidance on postoperative pain scores

No registrations found.

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

Summary

ID

NL-OMON29352

Source
NTR

Brief title
SOLAR

Health condition

Surgical patients

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: Medasense

Intervention

Outcome measures

Primary outcome

Postoperative pain score

Secondary outcome

(!) Postoperative opioid consumption as measured in the first 90 min of PACU stay
(2) Fentanyl use during anesthesia;
(3) Sevoflurane consumption during anesthesia;
(4) Inadequate hemodynamic events, see Table 1;
(5) Time between reversal of neuromuscular block and extubation/eyes open;
(6) Occurrence of awareness;
(7) Anesthesia and surgery times/PACU stay time.

Study description

Background summary

Inadequate (under-dosing) as well as excessive (overdosing) levels of analgesia and anesthesia are associated with poor patient outcome. Currently, the analgesic component of anesthesia is steered using traditional indices, such as heart rate and blood pressure. However, the use of these indirect parameters for nociception is inaccurate and often results in under- or overdosing of anesthetics. Recently a newly developed index, the Nociceptive Level (NOL) index was validated and showed superiority over heart rate and blood pressure in relation to intense and mild nociceptive stimuli. In this study we will assess the effect of NOL guided anesthesisa (fentanyl/sevoflurane/rocuronium) on postoperative pain and opioid consumption.
Objective
To guide the analgesic component of anesthesia using the NOL index in ASA 1-3 patients under general anesthesia for elective abdominal surgery.

Study design
A randomized, double blinded, controlled trial in which standard care anesthesia and NoL-guided anesthesia will be compared in ASA I-III patients requiring elective abdominal surgery under general anesthesia.

Study population
50 ASA 1-3 patients undergoing elective open abdominal surgery or laparoscopic/ robot-assisted abdominal surgery will.
Main end-points
1. Postoperative pain

Secondary end-points
1. Postoperative opioid consumption
2. Opioid and sevoflurane consumption in total dose and dose/min; and
3. Incidence (number of episodes) of inadequate anesthesia (as derived from heart rate, blood pressure, BIS values)

Study objective

We hypothesize that, compared with standard management, NoL-guided anesthesia will lead to reduced postoperative pain scores, and during anesthesia to increased hemodynamic stability.

Study design

Start June 28, 2019 - End June 28, 2020

Intervention

This is a double blind, randomized controlled superiority trial in which NOL-guided anesthesia will be compared to standard of care in ASA 1-3 patients undergoing elective open abdominal surgery or laparoscopic assisted abdominal surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age: 18 years and older;
2. ASA I-II-III

3. Elective open abdominal surgery or robot/laparoscopic assisted abdominal surgery.

Exclusion criteria

1. Unable to give written informed consent;
2. Use of epidural analgesia or local anesthesia (eg. transversus abdominal plain block, TAP block)
3. Non-elective surgery
4. Pregnancy/lactation.
5. BMI > 35 kg/m2;
6. Uncontrolled preoperative hypo- or hypertension (Mean arterial pressure < 60 mmHg or systolic blood pressure > 160 mmHg)
7. Preoperative Heart rate < 45/min or > 90/min;
8. Central nervous system disorder (neurologic/head trauma/uncontrolled epileptic seizures);

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-06-2019
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
NA

Ethics review

Positive opinion

Date:	28-06-2019
Application type:	First submission

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
NTR-new	NL7845
Other	METC-Leiden Den Haag Delft : METC-LDD P19.012

Study results

Summary results

NA