Nociceptive-Level (NoL)-guided analgia versus standerd practice during general remifentanil/propofol anesthesia in ASA 1-3 patients

No registrations found.

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

Summary

ID

NL-OMON27388

Source
NTR

Brief title
NoLA

Health condition

- Analgesia
- Anesthesia
- Nociceptive level index
- Intraoperative monitoring
- Haemodynamics

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Opioid and propofol consumption in total dose and dose/min; and

2. Incidence (number of episodes) and total duration of inadequate anesthesia

Secondary outcome

1. Differences in Pk (prediction probability) values of NoL, BIS, HR and MAP for predicting the balance of nociception-anti nociception during the following states

• Awake vs. loss of consiousness (LOC)

• Anesthesia (after discontinuation of propofol and remifentanil) vs. opening eyes

• LOC vs intubation

• Normal stimulation vs maximum stimulation (as indicated by the surgeon);

2. Incidence of NoL values < 10 and > 20;

3. Time from reversal of neuromuscular blockade to extubation;

4. Pain and sedation scores, incidence of nausea/vomiting, hemodynamics, respiration and medication use (e.g. opioids and antiemetics) in the recovery room obtained at 15-min interval;

5. PACU: time until Aldrete > 9 (readiness for discharge);

6. Incidence of memory/awareness.

Study description

Study objective

We hypothesize that, compared with standard management, NoL-guided anesthesia will lead to reduced incidence of inadequate anesthesia and increased hemodynamic stability. Furthermore, we hypothesize that NoL-guided anesthesia leads to reduced recovery times, reduced postoperative pain scores and PONV and faster PACU discharge (readiness) times.

Study design

Perioperative period: intraoperative analgesia consumption and haemodynamics; postoperative pain, medication use, nausea/vomiting

Intervention

Nociceptive level guided analgesia

Contacts

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Eligibility criteria

Inclusion criteria

1. Age: 18-80 years;

2. ASA I-II-III

3. Elective open abdominal surgery or 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 > 100 mmHg)

7. Preoperative Heart rate < 45/min or > 90/min;

8. Central nervous system disorder (neurologic/head trauma/uncontrolled epileptic seizures);

9. Illicit substance or alcohol abuse within 30 days;

10. Chronic use of pain medication within 30 days;

11. Chronic use of psychoactive drugs within 30 days;

12. Significant medical condition

a. Untreated or persistent peripheral or central cardiovascular disease

b. Severe pulmonary disease e.g. COPD gold 4 , FEV< 1.0 L/s, or (evidence of) elevated paCO2 > 6.0 kPa

c. Significant hepatic disease with increased bilirubin, INR or low albumin

13. Beta blocker use

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-07-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-02-2017
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	NL6002
NTR-old	NTR6500
Other	NL56370.058.15 : p16019

Study results