The NoLA study

No registrations found.

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

Summary

ID

NL-OMON28148

Source
Nationaal Trial Register

Brief title
the NoLA

Health condition

analgesia, anesthesia, anaesthesia, peroperative, opioid consumption, nociception, monitoring.
analgesie, anesthesie, perioperatief, pijn, nociceptie, opiaat consumptie,

Sponsors and support

Primary sponsor: Leiden Univeristy Medical Center
Source(s) of monetary or material Support: prof dr Albert Dahan

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

Background summary

The NoL is a multi-parameter non-linear combination of heart rate (HR), heart rate variability (HRV), amplitude of the finger photo-plethysmogram (AP), skin conductance, fluctuations in skin conductance, and their time derivatives, derived from Random Forrest regression. This is a unique algorithmic modeling approach that combines various inputs and identifies complex nonlinear interactions. In a previous study, the NoL outperformed the mean arterial pressure and heart rate as indices for nociception and anti nociception.

In this trial, we randomize 80 patients to receive either NoL guided anesthesia or standard of care anesthesia. We hypothize that NoL guided anetshesia will result in lower peroperative opioid consumption, greater hemodynamic stability and faster recoverytimes than standard of care anesthesia.

Study objective

We hypothesize that, compared with standard management, NoL-guided anesthesia will lead to reduced incidence of inadequate anesthesia (see Table 1) 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

Measurements will take place continuously from the moment the patient arrives in the OR to the moment the patient leaves the OR. This can take up to several hours.

In the PACU, measurements will take place every 15 minutes untill the patient is deemed fit for discharge to the ward based on pre-defined criteria.

Intervention

NoL-guided anesthesia versus standard of care.

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:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-07-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-10-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42622
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5799
NTR-old	NTR6074

Register	ID
CCMO	NL56370.058.15
OMON	NL-OMON42622

Study results