The NoLA study

Gepubliceerd: 28-10-2016 Laatst bijgewerkt: 19-03-2025

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...

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

Samenvatting

ID

NL-OMON28148

Bron
NTR

Verkorte titel
the NoLA

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden Univeristy Medical Center
Overige ondersteuning: prof dr Albert Dahan

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

NoL-guided anesthesia versus standard of care.

Contactpersonen

Publiek

Suzanne Broens
Leiden
The Netherlands

Wetenschappelijk

Suzanne Broens
Leiden
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: 18-80 years;

2. ASA I-II-III

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-07-2016
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-10-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42622
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5799
NTR-old	NTR6074
CCMO	NL56370.058.15
OMON	NL-OMON42622

Resultaten