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

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

Samenvatting

ID

NL-OMON27388

Bron
Nationaal Trial Register

Verkorte titel
NoLA

Aandoening

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

Ondersteuning

Primaire sponsor: Medasense
Overige ondersteuning: Medasense

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

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Nociceptive level guided analgesia

Contactpersonen

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Wetenschappelijk

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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:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-07-2016
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-02-2017

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6002
NTR-old	NTR6500
Ander register	NL56370.058.15 : p16019

Resultaten