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

Gepubliceerd: 28-06-2019 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON29352

Bron
NTR

Verkorte titel
SOLAR

Aandoening

Surgical patients

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: Medasense

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative pain score

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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

Onderzoeksopzet

Start June 28, 2019 - End June 28, 2020

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: 18 years and older;
2. ASA I-II-III
3. Elective open abdominal surgery or robot/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 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);

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-06-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
NA

Ethische beoordeling

Positief advies

Datum:	28-06-2019
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	NL7845
Ander register	METC-Leiden Den Haag Delft : METC-LDD P19.012

Resultaten

Samenvatting resultaten
NA