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

Published: 12-03-2019
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To guide the analgesic component of anesthesia using the NOL index in ASA 1-3 patients under general anesthesia for elective abdominal surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48484

Source
ToetsingOnline

Brief title
SOLAR

Condition

- Other condition

Synonym
anesthesia, pain

Health condition

perioperatieve patienten

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,De apparatuur wordt beschikbaar geteld door de firma Medasense; de firma zal ook de kosten van de dataanalyse afdragen aan het LUMC

Intervention

Keyword: anesthesia, opioids, pain

Outcome measures

Primary outcome

Postoperartive pain

Secondary outcome

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

Incidence (number of episodes) of inadequate anesthesia (as derived from heart

rate, blood pressure, BIS values)

Study description

Background summary

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

Study 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.

Intervention

NOL-guided versus standard of care anesthesia

Study burden and risks

None

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age: 18 years and older;
2. ASA I-II-III
3. Elective 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.
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 epileptische aanvallen);

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	20-06-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL68563.058.18

Study results

Date completed:	03-04-2020
Actual enrolment:	20