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

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To guide the analgesic component of anesthesia using the Nociceptive Level (NoL) index in ASA 1-3 patients under general anesthesia for elective abdominal surgery.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON42622

**Source**
ToetsingOnline

**Brief title**
NoLA

### Condition

- Other condition

**Synonym**
anesthesia, narcosis

**Health condition**

anesthesie/chirurgie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** anesthesia, monitoring, nociception, pain

## 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

(as derived from heart rate, blood pressure, BIS values and somatic arousal)

### 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

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.

### Study objective

To guide the analgesic component of anesthesia using the Nociceptive Level (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 burden and risks

None

# Contacts

**Public**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

**Scientific**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## 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

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|---|---|
| Study phase: | 2 |
| Study type: | Observational non invasive |
| 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): | 25-07-2016 |
| Enrollment: | 80 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 12-05-2016 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28148
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL56370.058.15 |
| OMON | NL-OMON28148 |

# Study results

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|---|---|
| Date completed: | 22-12-2017 |
| Actual enrolment: | 80 |