Experimental measurement of analgesia during anesthesia

Gepubliceerd: 15-01-2014 Laatst bijgewerkt: 19-03-2025

We hypothize that higher opioid doses will lead to a lower NOL.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24176

Bron
NTR

Aandoening

Intraoperative measurement nociception analgesia level

In het NL:
pijnmeting intraoperatief nociceptie pijnstilling

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain Response Index (continuous measurement allowing assessment).

Toelichting onderzoek

Achtergrond van het onderzoek

Despite various efforts there is still the need for adequate monitoring of pain and nociception during anesthesia. In previous studies we measured pain responses during anesthesia based on single end-points, eg heart rate, blood pressure and pulse transit time. None of these parameters provided sufficient
information regarding nociception. We therefore want to further investigate this matter using a composite parameter, the Nociception Level or NoL. The NoL is a novel index that measures the magnitude of the autonomic response to painful stimuli. The NoL combines information from several physiological parameters, which represent different autonomic pathways. This is a multi-parameter approach empowered with state-of-the-art
signal processing and machine learning techniques. The NoL has been shown to have strong association with intensity of the pain stimuli (see publications).

Doel van het onderzoek

We hypothize that higher opioid doses will lead to a lower NOL.

Onderzoeksopzet

Measurements will be performed just prior to 1) laryngoscopy (during and the 3-min following) and 2) intubation. The same will be done for insertion of the 3) gastric tube (if applicable), 4) bladder catheter (if applicable) and 5) skin incision.

Onderzoeksproduct en/of interventie

Study groups:
Group 1 (n = 12): PROPOFOL ONLY GROUP. In this study group measurements will be obtained before intubation or opioid administration. To that end plasma propofol concentration will be increased slowly from 0 to 4 µg/ml in steps of 0.5 µg/mL. After the highest target is reached, the propofol target concentration will be lowered to get a BIS value of 50. After 5-min, the laryngoscope will be inserted into the mouth. Next the laryngoscope will be removed. After 5-min the laryngoscope will be placed again and the patient will be intubated.
Group 2 (n = 12): PROPOFOL + REMIFENTANIL TARGET A. The subject will be intubated according to the design of group 1. The propofol concentration will be 1-2 µg/kg, aimed at a BIS of 50, with 1 ng/ml remifentanil.
Group 3 (n = 12): PROPOFOL + REMIFENTANIL TARGET B. The subject will be intubated according to the design of group 1. The propofol concentration will be 1-2 µg/kg, aimed at a BIS of 50, with 2 ng/ml remifentanil
Group 4 (n = 12): PROPOFOL + REMIFENTANIL TARGET C. The subject will be intubated according to the design of group 1. The propofol concentration will be 1-2 µg/kg, aimed at a BIS of 50, with 3 ng/ml remifentanil.

Group 5 (n = 12): PROPOFOL + REMIFENTANIL TARGET D. The subject will be intubated according to the design of group 1. The propofol concentration will be 1-2 µg/kg, aimed at a BIS of 50, with 4 ng/ml remifentanil.
Group 6 (n = 12): PROPOFOL + REMIFENTANIL TARGET E. The subject will be intubated according to the design of group 1. The propofol concentration will be 1-2 µg/kg, aimed at a BIS of 50, with 5 ng/ml remifentanil.
Group 7 (n = 12): PROPOFOL + REMIFENTANIL TARGET C. The subject will be intubated according to the design of group 1. The remifentanil target will be 3 ng/ml remifentanil. The propofol concentration will aim a BIS of 30.
Group 8 (n = 12): PROPOFOL + REMIFENTANIL TARGET C. The subject will be intubated according to the design of group 1. The remifentanil target will be 3 ng/ml remifentanil. The propofol concentration will aim a BIS 70.
5
In Group 1-6, propofol will be administered first to get a BIS of 50. Next remifentanil will be added and the propofol value will be altered such that BIS remains 50.

Contactpersonen

Publiek

Department of Anesthesiology
Leiden University Medical Center
PO BOX 9600
C.H. Martini
Leiden 2300 RC
The Netherlands

Wetenschappelijk

Department of Anesthesiology
Leiden University Medical Center
PO BOX 9600
C.H. Martini
Leiden 2300 RC
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Age: 18-80 years;
Sex: male or female;
Surgery: Any surgery under general anesthesia;
ASA status: 1, 2 or 3.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age: < 18 or > 80 years;
Unable to give written informed consent;
Pregnancy/lactation;
Extreme obesity: BMI > 35;
Perceived difficult intubation.
Patients requiring a rapid sequence induction
Patients on beta-blockers

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38899
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4265
NTR-old	NTR4401
CCMO	NL43511.058.13
OMON	NL-OMON38899

Resultaten

Samenvatting resultaten
Treister R et al. Differentiating between heat pain intensities: The combined
effect of multiple autonomic parameters. Pain. 2012 May 28.
2. Edry R et al. Non‐Linear multi‐parameter approach for evaluation of nociception
level during general anesthesia, Proc Conf American Soc of Anes Conf, Oct 2012.
3. Ben-Israel N, Kliger M, Zuckerman G, Katz Y, Edry R. Monitoring the nociception level: a multi-parameter approach. J Clin Monit Comput. 2013 Dec;27(6):659-68.