Measurement of nociceptive index during general anesthesia in ASA 1-3 patients undergoing elective surgery using the Nociception Level (NoL) index

Published: 15-05-2013
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Measurement of the pain index, NoL, during laryngoscopy, intubation and skin incission during variations in de level of propofol and remifentanil.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38899

Source
ToetsingOnline

Brief title
MEDASENSE studie

Condition

- Other condition

Synonym
Nociception, Pain

Health condition

patienten die een elective chirurgische ingreep ondergaan onder algehele anesthesie

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: measurement, nociception, pain, Surgery

Outcome measures

Primary outcome

NoL

Secondary outcome

Cardiovascular parameters incl. HR, BP and CO

Study description

Background summary

Despite various efforts there is still the need for adequate monitoring of pain and nociception during anesthesia. In our previous protocol 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. The 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.

Study objective

Measurement of the pain index, NoL, during laryngoscopy, intubation and skin incission during variations in de level of propofol and remifentanil.

Study design

Observational

Study burden and risks

We expect no study related side effect. Anesthesia related side effects include hypo/hypertension, brady/tachycardia

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

Patients undergoing elective surgery under general anesthesia

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-07-2013
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2013
Application type:	First submission
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

ID: 24176
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43511.058.13
OMON	NL-OMON24176