VALIDATION OF THE PMD-200 SAFETY, PERFORMANCE AND CLINICAL UTILITY IN SUBJECTS REQUIRING SURGERY UNDER GENERAL ANESTHESIA

Published: 21-07-2016
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To validate the PMD 200 NoL device

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43338

Source
ToetsingOnline

Brief title
Medasense-2 study

Condition

- Other condition

Synonym
anesthesia, pain

Health condition

patienten onder anesthesie

Research involving
Human

Sponsors and support

Primary sponsor: Medasense Bioemtrics
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Nociception, Pain, Surgery

Outcome measures

Primary outcome

NoL parameter

Secondary outcome

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Study description

Background summary

It is still difficult to get an indication of the nociceptive state of the patient during surgery under general anesthesia. Endpoints as blood pressure and heart rate are moderately reliable. The Medasense Nociceptive Level (NoL) monitor combines a number of measurements including, heart rate, heart rate variability, plethysmogram, skin resistance and derivatives of these parameters through a complex (black box) algorithm using machine learning technology to get a reliable estimate of the nociceptive state of the patient. In this study, the Nol monitor is validated via a number of stimuli that are administered prior to the study.

Study objective

To validate the PMD 200 NoL device

Study design

Randomized, single blind

Intervention

Application pain stimuli prior to surgery

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

Electie surgery
Age 18+
ASA1-3

Exclusion criteria

History of cardiac arrhythmia in the last 12 months
Allergy to study medication
neuromuscular disease
alcohol or drug abuse
beta-blocker use
Use of morhine > 30 mg/day

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2016
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-07-2016
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

No registrations found.

In other registers

Register	ID
CCMO	NL57922.058.16