Comparison of Adequacy of Anesthesia Monitoring with Standard Clinical Practice during Routine General Anesthesia

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Comparing to the control group where adequacy of anesthesia is monitored using NIBP, SpO2, ECG and NMT, the occurrence rate of inadequate anesthesia events, bradycardia and hypotension in subjects undergoing surgery is lower when Entropy and SPI…

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

Summary

ID

NL-OMON38660

Source
ToetsingOnline

Brief title
123.04-2012-GES-0009

Condition

- Other condition

Synonym
N.A.

Health condition

specifieke aandoeningen zijn niet van belang voor het onderzoek

Research involving

Human

Sponsors and support

Primary sponsor: GE Healthcare Attn: Petra Peltola, Clinical Research Manager
Source(s) of monetary or material Support: GE Healthcare;Finland

Intervention

Keyword: Adequacy of Analgesia, general anesthesia

Outcome measures

Primary outcome

• Incidence of hemodynamic instability including hypertension, hypotension, tachycardia and bradycardia

• Incidence of subject movements including somatic arousal, somatic response

Secondary outcome

• Amount of anesthetic and analgesic drugs used

• Time points of the operation (start of monitoring, induction, loss of consciousness, intubation, start of surgery, maximum surgical stimuli, end of surgery, discontinuation of anesthetics, open eyes on verbal command (emergence from anesthesia), extubation)

• In the recovery room, the modified Aldrete-Score, postoperative nausea and vomiting, and pain using a 0-10 numerical pain intensity rating (Visual Analog Scale, VAS) scale are recorded.

• On the first postoperative day, all subjects are asked by a blinded investigator if they had any memory or awareness during anesthesia and the level of satisfaction with the whole surgical procedure using a 0-100 scale.

• SPI and Entropy values from the test group

Study description

Background summary

This is a clinical multicenter study to demonstrate, that using SPI and Entropy in adjunct to other clinical information, decreases the occurrence rate of inadequate anesthesia events, bradycardia and hypotension in comparison to standard clinical practice during anesthesia. Current scientific literature suggests that using SPI and Entropy measurements gives at least as good indication of the level of analgesia compared to traditional approaches, such as observing physiological changes (hypertension, tachycardia, grimacing and movement during anesthesia).

Study objective

Comparing to the control group where adequacy of anesthesia is monitored using NIBP, SpO2, ECG and NMT, the occurrence rate of inadequate anesthesia events, bradycardia and hypotension in subjects undergoing surgery is lower when Entropy and SPI monitoring is used in addition to NIBP, SpO2, ECG and NMT.

Study design

This is a prospective post-market, multi-site, blinded (at postoperative stage, not in Operation Room), randomized, parallel comparison study

Intervention

extra non-invasive monitoring of Entropie and SPI to measure adequacy of analgesia

Study burden and risks

As patients get standard anesthesia with standard monitoring, no risk or burden is related to the study

Contacts

Public
GE Healthcare Attn: Petra Peltola, Clinical Research Manager

Kuortaneenkatu 2
Helsinki FI-00510

FI
Scientific
GE Healthcare Attn: Petra Peltola, Clinical Research Manager

Kuortaneenkatu 2
Helsinki FI-00510
FI

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age 18-80 years of age
• Surgery that is expected to last at least 2 hours under general anesthesia with endotracheal tube

Exclusion criteria

• Any subject with a cardiac pacemaker
• Any subject with atrial fibrillation at the time of obtaining the baseline values
• Any subject with more than 5 ventricular extra systoles/minute at the time of obtaining the baseline values
• Any subject who needs invasive blood pressure measurement
• Any subject who show hemodynamics that would have qualified for being considered as a sign of inadequate anesthesia already at baseline
• Any subject with epidural anesthesia or analgesia during the surgery. Epidural catheter may be placed pre-operatively, and used in the PACU, but not during the surgery
• Any subject having surgery that requires prone position
• Any subject with very high body mass index (>35) because of incompatibility with the target controlled anesthesia models used
• Any subject with known allergies to the specific anesthetic agents/ analgesic drugs

intended for use in their surgeries
• Any subject with laryngeal mask airway
• Any subject who is going to have major surgery with a high risk of extensive blood loss
• Any subject with known chronic use of opioids

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	19-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL44645.018.13