Measurement of nociception and prediction of movement during combined general (sevoflurane/fentanyl)-epidural anesthesia in ASA I-III patients undergoing major abdominal surgery using bilateral frontal EEG measurements and hemodynamic parameters (pulse transit time, cardiac output, blood pressure and heart rate)

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

Summary

ID

NL-OMON33353

Source
ToetsingOnline

Brief title
CVI

Condition

- Other condition

Synonym
analgesia, pain

Health condition

periopertieve pijn

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, EEG, masurement, pain

Outcome measures

Primary outcome

EEG parameters - movement during anesthesia

Secondary outcome

cardiac output and blood pressure

Study description

Background summary

Anesthesia has made enormous progress in the last couple of decades making surgery a reliable and safe procedure with minimal morbidity and mortality. Despite the progress many aspects of anesthesia remain elusive. Two important items that have recently been the focus of attention are the measurement of the depth of anesthesia and the measurement of nociception (or *pain-related afferent input*) during anesthesia. The current study will focus on the latter of these two items: measurement of nociception during anesthesia. In order to

get an indication of nociception we will make use of a recently developed index from the frontal EEG and EMG, the Composite Variability Index (CVI) by Aspect medical Systems. The CVI is based on the observations that the EEG-related variable BIS (bispectral index) rapidly responds to painful surgical stimuli during anesthesia and that the BIS waveform and EMG are more variable in case of a low analgesic load. This indicates that when insufficient amounts of analgesics have been infusion the BIS response (ie increase) to a surgical stimulus will be larger but also that the BIS and EMG display increased variability. The CVI is based on the standard deviation of BIS and EMG (sBIS and sEMG). The CVI combines sBIS and sEMG into a single measure of variability ranging from 0 to 100. Preliminary data suggest a possible predictive effect of the initial change in CVI just prior to a patient movement.

Study objective

In the current study we will measure CVI in ASA 1-3 patients during elective abdominal surgery under fentanyl/sevoflurane/epidural anesthesia. We will monitor patient movement as primary correlate to CVA and cardiovascular parameters as secondary correlates (eg, cardiac output, pulse transit time, blood pressure and heart rate).

Study design

Observational

Study burden and risks

Limited; a minor risk is expected from teh arterial line

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age: 18-80 years;
Sex: male or female;
Surgery: elective abdominal surgery lasting at least 2 hours. This includes gynecological procedures (eg., abdominal hysterectomies), urological procedures (eg., radical prostatectomies), GI-surgery (eg., colon surgery);
ASA status: 1, 2 or 3.

Exclusion criteria

Age: < 18 or > 80 years;
Unable to give written informed consent;
Pregnancy/lactation;
Extreme obesity: BMI > 35;
Perceived difficult intubation requiring muscle relaxation.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2009
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2009
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	NL28528.058.09