Changes in a composite variability index (CVI) and bispectral index (BIS) in response to standardized pain stimuli during propofol remifentanil infusion.

Published: 23-06-2009
Last updated: 05-05-2024

Main objective: to compare the accuracy of the changes in CVI in response to a standardized noxious stimulus during various targeted pseudo-steady-state concentrations of remifentanil and various steady state level of BIS as guided by propofol…

Ethical review	-
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33289

Source
ToetsingOnline

Brief title
Composite variability index versus BIS

Condition

- Other condition

Synonym
optimize anesthesia

Health condition

diepte van anesthesie tijdens operatie

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anesthesia, bispectral index (BIS), Composite variability index (CVI)

Outcome measures

Primary outcome

Changes of the BIS and CVI after a standard pain stimulus during various steady-state effect-site BIS levels and remifentanil as calculated by the software program Rugloop II (Demed Engineering, Temse, Belgium). Continuous bilateral BIS values throughout the study period.

Secondary outcome

to compare the changes in other vital signs such as heart rate and blood pressure compared to CVI in response to a standardized noxious stimulus during various targeted pseudo-steady-state concentrations of remifentanil and various steady state level of BIS as guided by propofol effect compartment controlled TCI (closed-loop).

Study description

Background summary

Measuring the two primary components of anesthesia, hypnosis and analgesia, are crucial in an attempt to optimize both hypnotic and analgesic drug delivery.
The Bispectral Index (BIS) is an EEG derived dimensionless number between 0 and 100 that has been proven to be adequate to measure the cerebral drug effect during hypnotic-anesthetic drug administration. It is an established mean to

prevent intraoperative awareness in the general surgical population and has been validated in numerous clinical trials.

Aside measuring the hypnotic component of anesthesia, measuring the nociception-anti-nociception balance during anaesthesia is considered crucial as it might be related to clinical outcome (1-3). The balance denotes the situation during which simultaneous opposite effects of nociceptive stimulation and anti-nociceptive medication on the physiology of the patient occur (4). Nociception caused by an injury or trauma during anaesthesia results in possible arousal reactions when accurate analgesia is lacking. Arousal is defined as a change in the hypnotic level of the patient as a result of an ascending stimuli reaching the cerebral cortex caused by a insufficient blockade at the subcortical level.

This *nociceptive cascade* can be blunted by administering anti-nociceptive medication such as opioids or local anesthetics. It has been show that analgesics decreases the variability of the BIS and blunt the increase in BIS that follows surgical stimulation (5, 6). Similarly, increases in electromyographic power (EMG) and its variability are associated with responses to painful stimulation. Recently, the composite variability index (CVI) was developed as a measure of this BIS and EMG variability. CVI is a unitless number between 0 and 100 and defined as the sum of the Mean sBIS (with 95% CI), the standard deviation of BIS over the previous one minute, at 15 second intervals and the mean sEMG (with 95% CI), the standard deviation of EMG over the previous one minute, at 15 second intervals. Previously, it has been shown that CVI is increased in responders to skin incision and correlates with pre-incision analgesic level. Also, it has been shown that both CVI and heart rate increases predict somatic responses during surgery. Hereby, CVI is a better predictor of somatic events than heart rate increases. (7, 8). Further studies are necessary to understand whether CVI would be a clinically useful indicator of inadequate analgesia various levels of anesthetic depth and analgesia. Therefore, the aim of this study was to compare the accuracy of the changes in CVI in response to a standardized noxious stimulus during various targeted pseudo-steady-state concentrations of remifentanil and various steady state level of BIS as guided by propofol effect compartment controlled TCI (closed-loop).

Study objective

Main objective: to compare the accuracy of the changes in CVI in response to a standardized noxious stimulus during various targeted pseudo-steady-state concentrations of remifentanil and various steady state level of BIS as guided by propofol effect compartment controlled TCI (closed-loop).

Secondary objectives: to compare the changes in other vital signs such as heart rate and blood pressure compared to CVI in response to a standardized noxious stimulus during various targeted pseudo-steady-state concentrations of

remifentanil and various steady state level of BIS as guided by propofol effect compartment controlled TCI (closed-loop).

Study design

prospective, randomized controlled

Intervention

pseudo-steady-state concentrations of remifentanil and various steady state level of BIS as guided by propofol effect compartment controlled TCI (closed-loop). protocol blz.8

Study burden and risks

The induction of anesthesia (until start of surgery) will be extended with 20 minutes. The electrical nociceptive stimulus might induce a shortlasting pain sensation in some of the patients (BIS target 70 and low concentration of remifentanil) as these patients might be sedated but not fully anesthetised.

Contacts

Public
Universitair Medisch Centrum Groningen

hanzeplein 1, Groningen
9713 GZ
Nederland
Scientific
Universitair Medisch Centrum Groningen

hanzeplein 1, Groningen
9713 GZ
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients: Age > 18 years and < 55 years
Study group: ASA class I and II patients requiring general anesthesia for elective surgical procedures

Exclusion criteria

patient refusal
weight less than 70% or more than 130% of ideal body weight,
neurological disorder
recent use of psycho-active medication, including alcohol.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	120
Type:	Anticipated

Ethics review

Not available

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	NL27457.042.09