CVI BIS study.

Gepubliceerd: 27-01-2010 Laatst bijgewerkt: 18-08-2022

When insufficient amounts of analgesics have been infused during anestesia, the BIS response a surgical stimulus will be larger and the BIS and EMG display increased variability (CVI).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24098

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center, dept of Anesthesiology
Overige ondersteuning: Aspect Medical systems

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

We will monitor patient movement and corresponding CVI & BIS values as a measure of adequate pain relief during surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

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 infused 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). It 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.

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 CVI and cardiovascular parameters as secondary correlates (eg, cardiac output, pulse transit time, blood pressure and heart rate).

Doel van het onderzoek

When insufficient amounts of analgesics have been infused during anestesia, the BIS response a surgical stimulus will be larger and the BIS and EMG display increased variability (CVI).

Onderzoeksopzet

From start of induction until end of surgery.

Onderzoeksproduct en/of interventie

Sixty ASA I-III patients for elective abdominal surgery will be given an epidural catheter prior to induction. After placement of the catheter, anesthesia will be started either with the

epidural anesthesia/sevoflurane + fentanyl in a high dose (7mcg/kg) or with a low (2mcg/kg) dose. No muscle relaxation will be used for intubation. Anesthesia will be maintained with sevoflurane and fentanyl bolus 2-3mcg/kg (high dose) vs 0,5-1mcg/kg (low dose) as judged by the attending anesthesiologist.

Contactpersonen

Publiek

Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Wetenschappelijk

Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: 18-80 years;

2. Sex: Male or female;

3. 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);

4. ASA status: 1, 2 or 3.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age: < 18 or > 80 years;

2. Unable to give written informed consent;

3. Pregnancy/lactation;

4. Extreme obesity: BMI > 35;

5. Perceived difficult intubation requiring muscle relaxation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2009
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-01-2010

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2076
NTR-old	NTR2193
Ander register	Department of Anesthesiology, LUMC : P09.114
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A