Assessment of the influence of intracranial space occupying lesions on the reliability of monitoring of the bispectral index for the detection of return of consciousness

Published: 17-12-2009
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Objective: Main objective: To assess whether BIS values at return of consciousness are different in patients with or without brain tumors.

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

Summary

ID

NL-OMON33118

Source
ToetsingOnline

Brief title
Influence of intracranial lesions on bispectral index

Condition

- Other condition

Synonym
return of consciousness

Health condition

Er wordt gekeken naar de anesthesie bij neurochirurgische patienten met en zonder hersentumoren Er wordt niet specifiek naar de aandoening onderzoek gedaan.

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: Bispectral index, consciousness, isolated forearm technique, lesions

Outcome measures

Primary outcome

To assess whether BIS values at return of consciousness are different in

patients with or without brain tumors.

Secondary outcome

Difference between left- and rightsided BIS values in patients with

supratentorial brain tumor during course of the study and at loss and return of

consciousness.

Comparison between predicted and measured propofol plasma concentrations during

course of the study and at loss and return of consciousness.

Study description

Background summary

The Bispectral Index (BIS) is a EEG derived dimensionless number between 0 and 100 that can be used to titrate intraoperative sedative drug dosing according to the patients individual needs. It is an established mean to prevent intraoperative awareness in the general surgical population (1). Although the use of BIS in neurosurgical patients has been described (2) the influence of intracranial lesions in the vicinity of the EEG recording electrodes, has not been systematically investigated yet.
A recently published investigation indicated that patients with brain tumors

might have higher BIS values at loss of consciousness and during intravenous sedation with propofol (3).
As this investigation did not assess the course of BIS at return of consciousness it is not sure whether the higher BIS values during sedation are a sign of a lesser cortical depressing effect of propofol and if the published guidelines for the intraoperative use of BIS are valid in patients with brain tumors. Since it is known that paralyzing agents might influence the calculated BIS values and the early and reliable recognition of return of consciousness is particular important in paralyzed patients, the proposed investigation will focus on the course of BIS at loss and the return of consciousness in paralyzed patients. Because a recently introduced upgrade from the BIS monitor (Aspect Vista®) allows bilateral monitoring, the impact of tumor location shall also be assessed.

Study objective

Objective: Main objective: To assess whether BIS values at return of consciousness are different in patients with or without brain tumors.

Study design

prospective, observational study

Study burden and risks

Due to the study protocol the total anaesthesia time will be prolonged by approximately 30 minutes. A tourniquet will be applied at the dominant side of the patients upper arm and inflated at suprasystolic values. The study participants will regain consciousness for a brief period of time after induction of anaesthesia. However, in previous investigations using the isolated forearm technique none of the patients remembered in postoperative interviews to be awake at any part of the procedure .

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

All patients: Age > 18 years
Study group: known intracranial pathology (recently obtained CT/MRI)
Control group: Neurosurgical patients without intracranial pathology

Exclusion criteria

Patient refusal
Significantly increased intracranial pressure
Uncontrolled arterial hypertension
Significant coronary artery disease
Anticipated difficult airway
Decreased level of consciousness
Existing motor weakness dominant arm/hand
Impaired hearing
Nausea, vomiting

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL27158.042.09