Changes of Effective Downstream Pressure (EDP) and Cerebral Perfusion Pressure (CPP) under influence of hypnotics and volatile narcotics. A prospective, randomised, double-blinded trial.

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Until now there has been a lack of investigations regarding the power of anaesthetics on the EDP.We will measure changes of EDP, CPPedp and autoregulation in each studie.- Study 1 : thiopental (5mg/kg) versus propofol (2mg/kg), - Study 2: etomidate...

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

Summary

ID

NL-OMON29763

Source
ToetsingOnline

Brief title
Effective Downstream Pressure (EDP) - influence of anesthetics.

Condition

- Other condition

Synonym
blood pressure, brain perfusion, cerebral effective dowstream pressure

Health condition

cerebraal-vasculaire vaatweerstand, autoregulatie hersenen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cerebral perfusion pressure (CPP), cerebral vasomotion, effective downstream pressure (EDP), hypnotics, narcotics

Outcome measures

Primary outcome

- EDP

Secondary outcome

- CPPedp (mmHg)

- Autoregulation phase relation between Vmca and the arterial pressure curve,

(ms)

- Difference between EDC calculation (Belford et al.) (mmHg)

and instantanious EDP measurement (Weyland et al.) (mmHg)

Study description

Background summary

Maintenance of sufficient cerebral perfusion is a very important factor influencing the outcome of patients undergoing general anaesthesia for surgical procedures and for patients with head injury.
Traditionally, cerebral perfusion pressure (CPP) has been measured as the difference between mean arterial blood pressure (MAP) and intracranial pressure (ICP). Recently, it has been shown that, in subjects without increased ICP, vascular tone determines the effective downstream pressure (EDP). It has been

suggested that zero flow pressure (ZFP), the arterial pressure at which blood flow ceases, represents the EDP of the cerebral circulation.
Transcranial Doppler-sonography (TCD) is used since the *80s to monitor cerebral circulation. Mean blood flow velocity of the middle cerebral artery (Vmca) is used instead of cerebral blood flow (CBF) measurements. This substitute seems appropriate because Vmca is directly proportional to blood flow of the middle cerebral artery as long as the cross sectional area of the insonated vessel does not change during a cardiac cycle. Using TCD, ZFP can be estimated by extrapolating the instantaneous relationship between arterial blood pressure and middle cerebral artery blood flow velocity to the point of zero flow. In theory ICP, CVP and cerebral vascular tone can all affect ZFP, thus the gradient between MAP and ZFP (= EDP) determines CPP.

Study objective

Until now there has been a lack of investigations regarding the power of anaesthetics on the EDP.
We will measure changes of EDP, CPPedp and autoregulation in each studie.
- Study 1 : thiopental (5mg/kg) versus propofol (2mg/kg),
- Study 2: etomidate (0,3mg/kg) versus midazolam (0,15 mg/kg),
- Study 3: desflurane 1MAC versus sevoflurane 1MAC

Study design

The trial will be performed prospective, randomised and double blinded. The measurement will be performed before, while, after induction of general anaesthesia.

Study burden and risks

The patient has to undergo: a pre- and intraoperative TCD examination, insertion of an invasive arterial catheter (a. radialis, risk 0.01%) in local anaesthesia and standardised interview with a questionnaire (ca. 20 min). The trial investigates induction and continuation of general anaesthesia. There will be no delay for the begin of surgery. The patient is at normal perioperative risk.

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

- Patients planed for surgical produre in general anaesthesia
- no intracranial surgery
- written informed consent
- 18 to 60 years old
- physical status ASA 1-2
- no history of cerebral illnes or cebrebrovascular deseases
- no medication with vasoactive therapeutics
(betabloker, alphabloker, nitrates, molsidomine, ACE-inhibitors, Ca-Antagonist, diuretics)

Exclusion criteria

- any cerebrovascular disease in history
- any history of cerebrovascular spasm
- any brain trauma in history
- any intracrainial neoplasma/tumor in history
- patients who cannot comunicate in Dutch or English language

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2007
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	28-06-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL12119.078.06