Brain metabolic changes during awake and asleep craniotomy measured by cortical microdialysis

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Does anesthesia itself or transition of anesthesia to an awake state and vice versa lead to changes in the lactate/pyruvate ratio, glucose, glycerol and glutamate concentration as measured in the brain interstitial fluid?Are the metabolic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON33779

Source
ToetsingOnline

Brief title
AWAKE study

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Structural brain disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
Brain Metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain, Metabolism, Microdialysis, Peroperative

Outcome measures

Primary outcome

Changes in brain metabolites (glucose, glycerol, lactate, pyruvate, glutamate)

Correlation between depth of anesthesia and brain metabolite changes

Secondary outcome

Difference in concentrations of metabolites between radiologically normal

tissue and abnormal brain tissue.

Brain propofol concentration in the three stages (anesthesia-awake-anesthesia)

Blood concentration of metabolites and propofol over time

Study description

Background summary

Patients undergoing brain surgery are anaesthetized by general anesthetics that induce hypnosis and analgesia. During anesthesia the metabolism of the brain alters, thereby contributing to the unconscious state of the patient. In particular, lowering of brain metabolism during anesthesia may support perioperative brain protection against stimuli such as ischemia and the production of reactive oxygen species. Currently, there are only limited reports available regarding the direct effects of anesthetics on brain metabolism. Such brain metabolic alterations have never been associated with patient level of consciousness. The present project focuses on the direct measurement of metabolic alterations in the subcortex of the brain during an awake state and under anesthesia in patients undergoing craniotomy during a so-called asleep-awake-asleep procedure. These direct measurements will be performed by microdialysis of interstitial brain fluids during surgery. We expect to confirm that anesthesia leads to alterations in brain metabolism compared to an awake state. In particular, metabolites as glutamate, glucose and lactate will increase due to reduced brain perfusion. In contrast, we

expect lower levels of pyruvate and glycerol during anesthesia.

Study objective

Does anesthesia itself or transition of anesthesia to an awake state and vice versa lead to changes in the lactate/pyruvate ratio, glucose, glycerol and glutamate concentration as measured in the brain interstitial fluid?
Are the metabolic alterations during anesthesia and full consciousness different in healthy or diseased brain areas (e.g. tumor tissue)?

Study design

Open, prospective, observational trial

Study burden and risks

The present study has a scientific merit and will not result in patient benefits. In general, the burden and risks associated with the present study are minimal. The catheters, needed for the measurements will be placed in tissue that will be subsequently removed during the operation. Therefore, there is no additional risk for brain tissue damage. With microdialysis, 144 µl of interstitial brain fluid metabolites will be sampled in the region surrounding the catheter. This will not disrupt the metabolic state in surrounding healthy tissue. Sampling can take place simultaneously during the normal operative procedure. It will therefore not delay or interrupt the treatment. All measurements will be stopped before the end of the operation.
Furthermore, blood sampling will be drawn from an arterial line that is placed preoperatively on a routine basis. Blood sampling will therefore not add up to patient discomfort. The total volume of blood that will be drawn is 10 x 10= 100 ml. Blood samples will be drawn from an existing arterial line, and will therefore not add up to patient discomfort.

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

Indication for awake craniotomy (asleep-awake-asleep-procedure) or asleep craniotomy
Age 18-80 years
Informed consent

Exclusion criteria

Diabetes mellitus
Anemia (Hb < 5 mmol/l)
Technical impossibility to place one catheter during the craniotomy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2009
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	09-03-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL26317.029.08