Non-invasive monitoring of mitochondrial oxygen consumption and oxygenation (COMET): observational clinical study.

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

Summary

ID

NL-OMON41866

Source
ToetsingOnline

Brief title
Clinical application COMET

Condition

- Other condition

Synonym
oxygen consumption and oxygenation mitochondrien

Health condition

basale fysiologie mitochondriele functie

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: Anesthesia, COMET, Mitochondrial, Oxygen

Outcome measures

Primary outcome

The mean and standard deviation of the mitoPO2 and mitoVO2 in mmHg. For the mitoVO2 and the mitoP50 measurements, the local mitochondrial oxygen supply will be blocked by pressure on the skin.

Primary Objective:

- Is the COMET clinically applicable? Is there the need for any practical or technical adjustments before implementing the technique on the intensive care?

- Is it possible to measure the mitoPO2, mitoVO2 and the mitoP50 during surgery on ASA1-2 patients. Are these results replicable and are these results comparable with the data from healthy volunteers?

Secondary outcome

Secondary Objectives:

- What will happen with the signal during induction of anaesthesia, what will generate vasodilatation? And in continuation what will happen with the signal when a vasopressor is given? In order to investigate this in a strictly observational study, our study population will be ASA 1-2 patients for intracranial tumour surgery; relatively few comorbidities, admitted to the ward

prior to surgery, and during surgery arterial pressure monitoring is standard

of care, as well as the administration of a vasopressor in order to achieve

haemostasis.

- Is the signal influenced by parameters other than seen in the animal models/

healthy volunteers?

- For the resection of intracerebral gliomas, ALA (gliolan) is used

systemically for fluorescence-guided resection. Is it possible to measure

mitoPO2 and mitoVO2 with systemically applied ALA, for future research?

Study description

Background summary

Mitochondrial function seems to play a key role in the development op sepsis, septic shock and optimization of erythrocyte transfusion trigger. So far our knowledge about mitochondrial function, is mainly obtained from ex vivo measurements on isolated mitochondria, mainly derived from animal biopsies. The development of the Protoporphyrin IX - Triplet State lifetime Technique (PpIX -TSLT), which is incorporated in the recently devolved COMET, makes continues, non- invasive monitoring of mitochondrial function possible. This technique is tested on healthy volunteers. The next step before implementation of this technique is to test in the clinic. The goal of this this observational clinical study is, to find out if the COMET is clinically applicable and secondly to get insight in the function of the mitochondria under different circumstances.

Study objective

The primary goal of this study is to get insight in the functionality of the COMET in the clinic. Secondly, since this will be the first continues mitochondrial oxygenation measurement in patients undergoing surgery, we want to obtain information about the mitochondrial oxygenation (mitoPO2) and oxygen consumption (mitoVO2) during vasodilatation (induction of anesthesia) and vasoconstriction (during vasopressor therapy).

Study design

single centre observational study

Study burden and risks

There are no direct benefits for the subjects enrolled in the study. Administration of ALA cream is safe. The risk of phototoxity after PpIX induction is considered low, because the COMET uses short-pulsed excitation and very low total light dosage. To limit the effects of phototoxity, the sight of the measurement will be coved with a plaster during 24 hours after the measurements. In the study with healthy volunteers. only local, transient skin irritations were seen, erythema, edema and hyper pigmentation

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

- Age 18-70 years
- Acceptable proficiency of the Dutch language
- ASA 1-2 patients, in order to limit the influence of co-morbidities on the mitochondrial function.
- Surgery for intracranial tumor;besides the inclusion of 40 patients for topical ALA application, we also will include 5 patients who receive ALA (gliolan) systemically for intracranial glioma resection, for further clinical research. In total 45 patients will be included.

Exclusion criteria

- allergy 5-aminolevuline
- No time to place plaster 3h prior to surgery
-When there no indication for invasive intra-arterial blood pressure monitoring
-Presence of Mitochondrial disease
- pregnancy/ lactation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2015
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-08-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-11-2015
Application type:	Amendment
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	NL51937.078.15