Cutaneous oxygenation and mitochondrial respirometry measurements, using the Protoporphyrin IX - Triplet State Lifetime Technique

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

Summary

ID

NL-OMON37834

Source
ToetsingOnline

Brief title
Mitochondrial oxygen measurements in the skin

Condition

- Other condition

Synonym
Mitochondrial oxygen measurements in the skin, standard values

Health condition

gezonde vrijwilligers

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW- Dit onderzoek maakt deel uit van een door ZonMW gefinancierde Life Sciences Pre-seed Grant met de titel A monitor for mitochondrial function in the intensive care. Het onderzoek volledig gefinancieerd worden door deze Grant.(Zie onderzoekdossier;bijlage G1)

Intervention

Keyword: - Mitochondrial Oxygen Tension (mitoPO2), - Protoporphyrin IX - Triplet State Lifetime Technique (PpIX-TSLT), - Protoporphyrin IX (PpIX), - Respirometry

Outcome measures

Primary outcome

The mean and standard deviation of mitoPO2 will be calculated in mmHg. The mitoVO2 and mitoP50 will be determined by a decrease in mitoPO2 after oxygen supply is blocked to the cells . The mitoPO2 will be recorded before during, and after a 90 second compression. The mitoVO2 is calculated from the decay of the mitoPO2 slope. With the Michaelis-Menten equation we can calculate MitoP50 in mmHg.

Secondary outcome

The practical applicability of the method will be tested by the researcher. If necessary adjustments will be made. The raw data of the measurements will be stored for extended off-line analysis of the signal quality. If necessary, we will look at opportunities to optimize the equipment.

The structure of the fluorescent signal, determines by means of the intensity of the detected signal (V) divided by time (minutes), expressed in V / minute.

The influence of skin temperature to the search parameters (mitoPO2, and

mitoVO2 mitoP50), will be determined at two different skin temperatures (34 and

40 degrees celsius).

Study description

Background summary

Sepsis and septic shock are life-threatening diseases. A early aggressive treatment of septic patients, by administering intravenous fluids and inotropy for improving the oxygen supply to the cells leads to a improved survival outcome. When the same treatment is applied at a later stage of the disease the treatment shows no improvement, and possibly leads to more damage. That a adequate tissue perfusion in this later phase does not improves prognosis, may be explained by a impaired mitochondrial function. Monitoring of these mitochondrial function has not been possible till to day. The PpIX triplet state lifetime measurement (PpIX-TSLM) technique, for measurement of mitochondrial oxygen tension (mitoPO2), oxygen consumption (mitoVO2) and the the affinity for oxygen to the mitochondrial respiratory chain (mitoP50), provides a potential means to do so. For the clinical use in human a concept is developed by using the topically administered 5-aminolevulin. Before this concept can be successfully developed, it is necessary to gain more knowledge about the normal values of the parameters measured under physiological conditions.

Study objective

The primary objective of this study is to gain more knowledge about the mean and the distribution of mitochondrial oxygen tension (mitoPO2), the mitochondrial oxygen consumption (mitoVO2) and the affinity for oxygen of mitochondrial respiratory chain (mitoP50) in the skin. Measured by cutaneous-PPIX TSLT technique under physiological and resting conditions.

Secondary, we hope to gain a better insight into the signal quality in human skin and the practical aspects of measurement in humans.

Study design

Observational single centre study pilot study.

Study burden and risks

The PPIX-TSLT technique shows some relationship to the principle of photodynamic therapy. Possible side effects will resemble the side effects from this therapy. The expectation is that these will not be occur. Fot that reason the lightload at the cutaneous-PPIX TSLT is much lower than in photodynamic therapy. Possible side effects may include: A burning pain during the measurement itself. And temporary the measurement can give, crusta, erythema and / or pigmentary changes of the skin afterwards.

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

- Speaking Dutch
- Age between 18 and 30 years.

- Healthy subjects

Exclusion criteria

- Non healthy subjects

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-12-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-10-2012
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	NL37911.078.11