The association between aging or chronic diseases and mitochondrial oxygenation and oxygen consumption as measured with the Protoporphyrin IX Triplet State Lifetime Technique

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

Summary

ID

NL-OMON51166

Source
ToetsingOnline

Brief title
Aging, chronic disease, mitoPO2 and mitoVO2

Condition

- Other condition

Synonym
aging, seniority

Health condition

Veroudering

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Aging, Chronic disease, Mitochondria, Oxygen

Outcome measures

Primary outcome

MitoPO2 (mmHg). Ten mitoPO2 (mmHg) baseline measurements will be performed on both the sternum and upper arm of all subjects. The mean and standard deviation of those measurements will compute the baseline mitoPO2 for every participant.

Secondary outcome

MitoVO2 (mmHg/second). Applying pressure on the probe will cause a temporary halt of circulation to the mitochondria. As the oxygen consumption continues, this will result in a time-dependent decrease in mitoPO2 from which the mitoVO2 can be calculated in mmHg/second. Three mitoVO2 measurements will be performed on both the sternum and the upper arm and the mean will be calculated for both.

Study description

Background summary

A new technique to measure mitochondrial oxygen tension was recently developed and calibrated by our lab. With this technique, mitochondrial oxygen tension *mitoPO2* and mitochondrial oxygen consumption *mitoVO2* can be measured in human skin. This led to the introduction of the COMET, an acronym of Cellular Oxygen METabolism (COMET, Photonics Healthcare B.V. Utrecht) which enables bed-side monitoring of mitoPO2 and mitoVO2 in real-time. Previous studies have

illustrated the potential of these measurements in various clinical conditions, unfortunately the influence of aging and chronic disease has not been examined. Before the COMET monitor can be used in clinical settings, it has to be known if these factors have any influence on the measurements. This study will therefore, examine the association between age and mitoPO2 and mitoVO2 values. Secondly, it will investigate whether there is any association between comorbidity and mitoPO2.mitoVO2. Lastly, the study will evaluate if mitoPO2 and mitoVO2 values differ between measurement location namely, the upper arm or sternum. This is because measurement locations vary in different clinical settings.

Study objective

The primary objective of this study is to observe the association between age and mitoPO2 values. The secondary objective is to evaluate whether there is also an association between age and the mitoVO2 values. Further objectives are to investigate the association between diabetes, obesity and neurodegenerative diseases and mitoPO2 and mitoVO2 values. Lastly, the study will evaluate whether mitoPO2 and mitoVO2 values differ between measurements done on the upper arm or the sternum.

Study design

Single center observational trial in healthy volunteers and patients with diabetes, obesity or neurodegenerative disease.

Study burden and risks

The intracellular oxygen measurements is a non-invasive measurement technique. The specific discomfort for the subject is the aminolevulinic acid containing-plaster that makes the skin sensitive for light. This plaster is applied on the skin at least five hours before measurement. The participants will not benefit directly from participation of the study. It will cost the patients about an hour of extra time. Overall the risks are considered negligible and the burden low. The study will aid in the development of new techniques to improve therapy strategies for various diseases. Therefore the group related benefits outweigh the risks in this study.

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

Healthy volunteers
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Aged between 18 years of age and 90 years of age
- Acceptable proficiency of the Dutch language
- Healthy volunteers without physical or mental illness

Comorbidity group
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Aged between 18 years of age and 90 years of age
- Acceptable proficiency of the Dutch language
- One of the underlying illnesses: neurodegenerative disease, diabetes mellitus type II or obesity (BMI>30), no other relevant comorbidity

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded

from participation in this study:
- Porphyria
- Known intolerance to components of the ALA plaster
- Presence of mitochondrial disease
- Pregnancy/lactation
- Patients with skin lesions on the measurement location which impede measurements
- Incapability to provide inform consent, due to a mental condition interfering with the ability to understand the provided information

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-05-2021
Enrollment:	319
Type:	Actual

Medical products/devices used

Generic name:	COMET
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-05-2021
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

ID: 25614
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76685.078.21