Measurement of non-invasive mitochondrial oxygenation and metabolism in healthy volunteers over time

Published: 26-09-2018
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Showing stability of mitoPO2 and ODR in healthy volunteers during 4 time points in a day

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

Summary

ID

NL-OMON45862

Source
ToetsingOnline

Brief title
MITOtime

Condition

- Other condition

Synonym
cellular oxygen metabolism, Mitochondrial function

Health condition

Mitochondriale oxygenatie

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: Mitochondria, Oxygen

Outcome measures

Primary outcome

mitochondrial oxygen concentration (mitoPO2) en oxygen disappearance rate (ODR)

Secondary outcome

Heart rate

Non invasive bloedpressure

respiratory rate

Temperature

Sickness score

Study description

Background summary

Measuring mitochondrial oxygen tension is possible with a novel technique developed by our lab. Demonstrating the stability of measurement of mitochondrial oxygen tension (mitoPO2) and oxygen disappearance rate (ODR) in healthy volunteers is a necessary step in the development of a new clinical monitor for mitochondrial function.
In previous research we found a detoriaton of mitoPO2 and ODR in an endotoxemia model in healthy volunteers. Showing stability of the measurements of mitoPO2 and ODR in a time control group will help interpreting the data. Furthermore showing stability of mitoPO2 and ODR over time will help with further research.

Study objective

Showing stability of mitoPO2 and ODR in healthy volunteers during 4 time points

in a day

Study design

Single centre study with healthy volunteers in the Erasmus Medical Centre

Intervention

ALA plaster Pp-IX accumulation in the skin. This enables the mitochondrial oxygen tension measurement.

Study burden and risks

The intracellular oxygen measurement is a non-invasive measurement technique. The specific discomfort for the subject is that an aminolevulic acid containing-plaster is applied that makes the skin sensitive for light. This plaster is applied on the skin 5-8 hours before the measurement. The measurement device is called the COMET monitor, able to measure cutaneous mitoPO2 and ODR by means of oxygen-dependent quenching of delayed fluorescence of mitochondrial protoporphyrin IX.

Overall, the study comes with a negligible risk and the burden is low.

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

* 18-35 years of age

Exclusion criteria

* Mentally disabled
* Presence of mitochondrial disease
* Porphyria
* History of atrial or ventricular arrhythmia
* (Family) history of myocardial infarction or stroke under the age of 65 years
* Cardiac conduction abnormalities on the ECG consisting of a 2nd degree atrioventricular block or a complex bundle branch block
* Hypertension (defined as RR systolic > 160 or RR diastolic > 90)
* Hypotension (defined as RR systolic < 100 or RR diastolic < 50)
* History of renal impairment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	9
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-09-2018
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	NL65767.078.18