Calibration of non-invasive measurement of mitochondrial oxygenation in healthy volunteers

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Calibration of the mitochondrial oxygen tension technique in the human skin

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

Summary

ID

NL-OMON44178

Source
ToetsingOnline

Brief title
cal-MitoPO2

Condition

- Other condition

Synonym
Human measurement technique calibration

Health condition

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

Pp-IX lifetime

Secondary outcome

Bloedgas analysis

Mitochondrial respiration

Temperature

Demografic data

Microvasculair data (flow and saturation)

Bloodpressure and heartfrequency

Study description

Background summary

A new in vivo technique to measure mitochondrial oxygen tension was recently developed by our lab and at this moment the first trials are performed with the clinical monitor. A small but significant difference between oxygen tension levels is observed between the new measurements and the earlier data (experimental research and data from other devices published elsewhere).
To make sure correct values are shown a two-point calibration should be done for this device. Using an arterial blood gas sample, an incubator and a short period of reversible inhibition of mitochondrial function on skin a two-point calibration could be done in vivo in healthy volunteers.

Study objective

Calibration of the mitochondrial oxygen tension technique in the human skin

Study design

a study in healthy volunteers.

Intervention

ALA plaster Pp-IX accumulation in the skin. This enables the mitochondrial oxygen tension measurement.
Mitochondrial respiration inhibition cream to make the oxygen tension the cells temporary equal to the oxygen tension in the blood.

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 mitoVO2 by means of oxygen-dependent quenching of delayed fluorescence of mitochondrial protoporphyrin IX.
An arterial blood sample is needed for this calibration to determine the oxygen tension, performed by skilled clinicians. Reversible inhibition of the electron transporter chain is achieved by topical application of cyanide, in a very low dose. Toxicity of cyanide differs per entrance way, by topical application on skin the LD50 is estimated at 100mg/kg bodyweight. {Harper:1997} We intent to give an aliquot of maximal 1 ml with the concentration 10mg/gr KCN in lanette crème. The measurement area is 2 cm2, on this area the cyanide cream is applied. The estimated amount of crème used on the skin is at most 10mg. the COMET measurement system will measure trough the layer of crème, therefore the amount of crème should be at most 10mg, because the optical properties of lanette crème will otherwise block the fluorescent signal from the skin. The amount of crème used will be measured on a laboratory calibrated precision scale.

For an average person (70kg) 10mg KCN / 70kg is 0.143mg/kg on the skin, this is at most 0.0143% of the LD50 for a person 70 kg of weight. In contrast the concentration of hydrogen cyanide (HCN) in tobacco smoke can be as large as 1.5 mg for a single cigar1, and 0.5 mg in a single cigarette2. No relevant toxicity is expected when applying 0.0143% of the LD50.

Previous to this study during a live demonstration of the COMET on targeting mitochondria(2015) in Berlin.
This measurement setup demonstration can also be seen at the website of Photonics Healthcare bv. www.photonicshealthcare.com

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

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy volunteer

Exclusion criteria

Mentally disabled
Presence of mitochondrial disease
Diabetic

Other deceases that may influence the mitoPO2 such as:
Anemia
Hemoglobinopathy
mild COPD
Porphyria
Positive Modified Allen Test: ulnar arterial flow in the hand is insufficient

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	15-01-2018
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	NL61767.078.17

Study results

Date completed:	26-03-2019
Actual enrolment:	21