The effect of arterial oxygen content on mitoPO2 in healthy human volunteers

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To determine the effect of SaO2 and PaO2 levels on mitoPO2 and markers of oxygen delivery and consumption in healthy human volunteers.

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

Summary

ID

NL-OMON52136

Source
ToetsingOnline

Brief title
MitoPO2 and arterial oxygen

Condition

- Other condition
- Respiratory disorders NEC
- Decreased and nonspecific blood pressure disorders and shock

Synonym
lack of oxygen, mitochondria

Health condition

Beademing

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: ESICM NEXT grant

Intervention

Keyword: hyperoxia, hypoxia, mitochondria, mitopo2

Outcome measures

Primary outcome

Difference in mitoPO2 and mitochondrial oxygen consumption at several oxygen saturations.

Secondary outcome

1. To determine whether ALA-uptake in the skin can be enhanced by using a dermaroller

2. To determine the effect of hyperoxia and hypoxia on markers of mitochondrial function and their relation to mitoPO2.

Study description

Background summary

The effect of low arterial oxygen saturation on cellular hypoxia remains unknown. Even though the administration of oxygen is common in the ICU and perioperative setting, physiological insight into its effect to prevent cellular hypoxia is lacking. Also, there is concern about toxicity. Consequently, the optimal oxygen saturation in critically ill patients is still a matter of controversy. The ability to measure the mitochondrial oxygen tension non-invasively using the PpIX-technique allows for clinical investigation into the effect of hypoxia and hyperoxia on mitochondrial oxygenation and oxygen consumption.

Study objective

To determine the effect of SaO2 and PaO2 levels on mitoPO2 and markers of

oxygen delivery and consumption in healthy human volunteers.

Study design

Physiological human volunteer study

Intervention

Hypoxemia (saturation of 85%) and hyperoxemia (up to FiO2 100%)

Study burden and risks

short episodes of hypoxia and hyperoxia carries minimal to no risk in healthy individuals. Participants could experience slight physical and psychological discomfort by placement of the arterial cannula, and temporary loss of mental focus associated with low oxygen breathing. The measurements will be done in a time span of 6 hours in a ICU environment. In total 40ml of blood will be drawn per volunteerpatient, evenly spaced over 5 timepoints. This volume is negligible compared to total blood volume and not associated with harm. Participants will not have any personal benefit. Results are likely to benefit future patients in the ICU or patients needing to undergo surgery.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age 18-30 years
healthy participants: absence of active or chronic disease, not taking medication
BMI 18-25kg/m2

Exclusion criteria

Participation in an investigational drug study within 3 months prior to screening
Allergy to plaster adhesives
History of photo dermatosis or porphyria
High altitude exposure in previous 3 months >1500m
Active smoking
History of cardiovascular disease
family history of myocardial infarction with age < 50 years
Evidence of conduction abnormalities or previous myocardial ischemia on EKG

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2022
Enrollment:	9
Type:	Actual

Ethics review

Approved WMO

Date:	21-02-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL79079.100.22