Quantitating reactive oxygen species (by Flow Cytometry) in healthy volunteers day-by-day.

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To validate a flowcytometry assay which can measure ROS day-by-day with healthy volunteers and CABG patients.

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

Summary

ID

NL-OMON42106

Source
ToetsingOnline

Brief title
Quantitating ROS in healthy volunteers

Condition

- Other condition

Synonym
free-radicals, Oxidative stress

Health condition

Oxidatieve stress

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Flow cytometry, Hyperoxia, Oxidative stress, Reactive oxygen species

Outcome measures

Primary outcome

ROS production

Secondary outcome

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Study description

Background summary

Hyperoxia stands for a high concentration of oxygen in blood. Hyperoxia leads to adverse effects, for example to important circulatory effects. The hypothesis is that hyperoxia causes vasoconstriction in the microcirculation, which causes an increase in systemic vascular resistance. The increase in vascular resistance causes a reduction of the cardiac output to keep the blood pressure constant.

Optimal PaO2 levels are unknown. To determine an optimal PaO2 range, it is important to quantify oxidative stress because it appears related to hyperoxia. Oxidative stress is defined as an imbalance between the production of ROS and anti-oxidants defence system. ROS has the potential to cause damage to lipids, proteins and DNA.

To investigate pathologies involving oxidative stress, it is important to reliably measure ROS production. Indirect methods are generally used, which measure end products of oxidative stress (F2-isoprostanes). Direct methods for ROS production are preferred but are difficult to perform, because ROS are highly reactive and results are hard to reproduce (analytical and pre-analytical factors are of great influence).

Currently, we have an assay that is capable of directly measuring ROS under

strict conditions. We are in progress of optimizing said assay, so that it can be applied in clinical trials investigating oxidative stress.

Study objective

To validate a flowcytometry assay which can measure ROS day-by-day with healthy volunteers and CABG patients.

Study design

To evaluate the assay we will perform measurements in 5 healthy volunteers and in 5 CABG patients. Of the healthy volunteers, 3 blood samples will be collected over 3 consecutive days. Since these healthy volunteers are expected to have a low and steady production of ROS, we anticipate to see this reflected in our assay. Additionally, these measurements will give us insight into the inter-assay variation. In the CABG patients, a total of 3 blood samples will be taken perioperatively (before, during and 12 hours after surgery) and the results will be compared with our current assay. To determine inter-assay variation, all measurements will be performed in triplicate.

Study burden and risks

Study subjects will undergo three venipunctures. Stress and risks are negligible.

Contacts

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Scientific
Selecteer

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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
> 18 years or older

Exclusion criteria

Hospitalization

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL50990.029.14