A Single-Center, Prospective Study in Healthy Volunteers for Validation of the O3 Regional Somatic Tissue Oxygenation Monitor

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49641

Source
ToetsingOnline

Brief title
O3 validation study

Condition

- Other condition

Synonym
regional tissue oxygenation, shortness of oxygen

Health condition

Anesthesiology, validation of non-invasive equipment in healthy volunteers

Research involving

Human

Sponsors and support

Primary sponsor: MASIMO
Source(s) of monetary or material Support: MASIMO Coorporation

Intervention

Keyword: hypoxia, O3 regional somatic tissue oxygenation, oxygen, validation study

Outcome measures

Primary outcome

The agreement between Masimo O3 derived somatic tissue rSO2 and invasively

determined somatic oxygenation values (SaO2 / SvO¬2, 30:70 ratio).

Secondary outcome

Evaluation of the association between SvO2 values derived from the tip of the

catheter in the renal vein, and from the femoral vein.

Study description

Background summary

In perioperative medicine, maintenance of tissue oxygenation is of paramount importance to prevent organ damage and development of (post-operative) complications. The Masimo O3 regional oximeter allows measurement of regional tissue oxygenation (rSO2) using near-infrared spectroscopy, allowing continuous monitoring of rSO2 of the tissue(s) of interest. The absolute and trend accuracy of the O3 oximeter at baseline and hypoxic states revealed acceptable results for cerebral tissue when compared to the reference gold standard (blood samples). However, during hypoxia, the absolute accuracy of somatic rSO2 values with invasive reference values is unknown.

Study objective

The objective of this study is to assess the performance of the Masimo O3 regional oximeter on somatic tissue oxygenation, under controlled hypoxia. Somatic rSO2 values will be compared with combined arterial and venous blood

gas measurements from vessels draining the blood from the respective measurement sites.

Study design

This study is a prospective, single-center healthy volunteer validation study.

Intervention

In all volunteers, a radial artery catheter will be inserted, as well as a femoral venous catheter via a sheath, so that blood can be drawn from the tip of the catheter (located in the renal vein) and from the femoral vein. O3 sensors will be placed bilaterally (when possible) on the flank superficial to the kidney, and quadriceps muscles, the latter preferably at a high muscle density location. rSO2 sensors will be placed on the forehead as well.
During interventions, volunteers will be allowed to breathe standardized oxygen concentrations using a tight-sitting facemask or mouth-piece. Each volunteer will undergo the *stepped hypoxia plateau sequence protocol*: Breathing mixtures of N2 in air via a tight-fitting facemask or mouth-piece, as determined by the preference of the volunteer. The FiO2 will be set at 0.21 (room air, baseline) and will be reduced in a stepwise fashion to achieve SpO2 values of 95%, 90%, 85%, 80%, 75% and 70%.
During baseline and during all subsequent SpO2 plateau intervals, paired whole blood reference samples from the arterial and femoral venous access points will be drawn.

Study burden and risks

Non-invasive measurement risks: The risk from non-invasive devices is minimal since the measurement is non-invasive and uses optical technology.

Sensor risks: As with all optical sensors, the investigational device has the theoretical risk of thermal burn. The design includes safeguards, and this risk is believed to be very low. Sensors will be attached with adhesive, and may be secured by a supplemental headband. Pressure damage may occur to the tissue if the sensor is placed too tightly. This risk is believed to be low. Optical exposure is minimized by procedure and low power. This risk is believed to be low.

Stepped Hypoxia Plateau Sequence Protocol: The risks of the brief exposures to hypoxia include feeling short of breath, headache, and dizziness. Brief loss of consciousness may occur, but is not expected at the levels of oxygen targeted for these tests given the magnitude of comparable studies, in which none of these events occurred.

Femoral venous catheter placement: ultrasound-guided insertion of a femoral

venous sheath and sampling catheter is regarded safe for short-term use. It is associated with a low incidence of serious complications, such as renal thrombosis. To prevent renal thrombosis, a low dose of heparin will be administered locally via the tip of the catheter. The most common complication of the femoral venous cathether placement is local hematoma. Catheterization is performed by experienced and qualified interventional radiologists. Correct positioning of the proximal tip of the catheter (at the level of the renal vein) will be ensured by x-ray or fluoroscopy, which has a negligible long-time carcinogenic risk, and low-dose intravenous contrast medium, which is safe in volunteers with no history of allergy.

Radial artery line placement: Arterial catheters have been found to be relatively safe with a low incidence of serious complications. Typical complications include temporary radial artery occlusion and hematoma. (Very) rare complications (less than 1% of procedures) include localized catheter site infection, hemorrhage, sepsis, permanent ischemic damage and pseudo-aneurysm formation.

Both the use of the femoral venous catheter, as well as the stepped hypoxia plateau sequence protocol methods is similar to the standard protocols recommended by the FDA and ISO Standards for testing pulse oximeters with mild hypoxia steps and blood drawn from arterial catheters (ISO 80601-2-61:2011).

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

* Age between 18 and 45 years
* Willing and able to provide written informed consent
* Healthy volunteer

Exclusion criteria

* Pregnant women (female subjects will have a pregnancy test prior to being admitted to the study).
* Presence of any cardiovascular or pulmonary disease
* Exposure to high altitude(s) (>2000 m) within 30 days prior to the study
* Known allergy to intravenous contrast medium or heparin
* Volunteer has skin abnormalities affecting the digits such as psoriasis, eczema, angioma, scar tissue, burn, fungal infection, substantial skin breakdown, nail polish or acrylic nails that would prevent monitoring of SpO2 levels during the study
* Patients deemed not suitable for the study at the discretion of the Investigator

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-11-2020
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	O3 Regional Somatic Tissue Oxygenation Monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-11-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-02-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-05-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
ClinicalTrials.gov	NCT04584788
CCMO	NL75041.028.20

Study results

Date completed: 02-06-2021

Results posted: 10-02-2022

First publication
27-01-2022