A Single-Center, Prospective Study in Healthy Subjects to Validate a New OXYGEN RESERVE INDEX (ORI)

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

Summary

ID

NL-OMON41998

Source
ToetsingOnline

Brief title
OXYGEN RESERVE INDEX (ORI)

Condition

- Other condition

Synonym
Oxygen Reserve Index, pressure of O2

Health condition

zuurstofspanning en zuurstof saturatie bij gezonde vrijwilligers

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hyperoxic, normoxic, oxygen, oxygen reserve index

Outcome measures

Primary outcome

Validation of the new Oxygen Reserve Index (ORI) by collecting optical data

using the Rainbow SET Pulse CO-Oximeter (Masimo Corp.) and comparing them to

whole blood references of arterial and venous blood drawn in healthy

volunteers.

Secondary outcome

• Determination and quantification of the capability of the new Oxygen Reserve

Index (ORI) to serve as an early alarm of changes in patient*s oxygen status

• Quantification of the effects of changes in inspired oxygen concentration on

o cerebral tissue oxygenation (as obtained by near infrared spectroscopy, NIRS).

o peripheral tissue oxygenation (as obtained by NIRS).

Study description

Background summary

Monitoring a patient*s oxygen status during anesthesia using pulse oximetry is essential. The new Oxygen Reserve Index (ORI) may help provide clinicians real-time visibility to oxygenation in a moderate hypoxic range and serve as a warning of an impending hypoxic state. In this way, ORI may enable proactive interventions to avoid hypoxia

Study objective

The primary objective is to validate the new Oxygen Reserve Index (ORI) by collecting optical data using the Rainbow SET Pulse CO-Oximeter (Masimo Corp.) and comparing them to whole blood references of arterial and venous blood drawn in healthy volunteers.

Study design

Prospective first in human validation intervention study at one single center

Intervention

Each subject will undergo the following interventions
• Change in inspiratory oxygen fraction (FiO2):
• Normoxia: room air (FiO2 0.21) (baseline)
• Hyperoxia: 100% oxygen (FiO2 1.0)
• Hypoxia: breathing mixtures of N2 in air via a tight fitting facemask to reach arterial oxygen saturation levels of just below 90%, 80%, and eventually 70% as measured by pulse oximetry (Radical 7, Masimo Corp.)
• Change in expiratory carbon dioxide concentration (etCO2) (during normoxia, awake state):
• Normoventilation (etCO2 4.5 - 5 Vol%)
• Partial rebreathing or adding external medical CO2 (target etCO2 7 - 7.5 Vol%)
• Hyperventilation (target etCO2 2.5 - 3 Vol%)
• A vascular occlusion test (VOT) will be performed by inflating an upper arm blood pressure cuff at each intervention.

Study burden and risks

Noninvasive measurement risks: The risk from noninvasive pulse oximeter devices is minimal since the measurement is noninvasive and uses optical technology similar to conventional pulse oximetry. Sensor risks: As with all optical sensors, the investigational device has the risk of thermal burn. The design includes safeguards, and this risk is believed to be low. Pressure damage may occur to the tissue if the sensor is placed too tightly. Sensors will be attached with adhesive, and may be secured by a supplemental headband. This risk is believed to be low. Optical exposure is minimized by procedure and low power. This risk is believed to be low. Radial artery line placement: Arterial catheters have been found to be relatively safe with a low incidence of serious complications. Common complications include temporary radial artery occlusion and hematoma. Less common complications (less than 1% of procedures) include localized catheter site infection, hemorrhage, sepsis, permanent ischemic damage and pseudoaneursm formation. Arterial draws: The most common complications associated with arterial draws are hematoma and bruising. Oxygen desaturation 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. Benefits: There will be no direct benefits to the enrolled volunteers. Future benefits to patients might include a reduction in invasive procedures due to the ability to trend moment-by-moment physiological variables such as cerebral oximetry

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
•Written informed consent
•Healthy subjects

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-09-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Rainbow SET Pulse CO-Oximeter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-05-2015
Application type:	First submission
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	nct5047
CCMO	NL52290.028.15