Extended SpO2: A method for determining carbon dioxide pressure in arterial blood.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35819

Source
ToetsingOnline

Brief title
Extended SpO2 study

Condition

- Respiratory tract therapeutic procedures

Synonym
assisted ventilation, oxygen saturation, pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Sponsor: Philips Research

Intervention

Keyword: Bohr-Haldane effect, carbon dioxide, oxygen saturation in blood, pulse oxymetry

Outcome measures

Primary outcome

The venous and arterial bloodgas values

Secondary outcome

nvt

Study description

Background summary

Study the feasibility of extending the SpO2 sensor functionality towards arterial CO2 monitoring. SpO2 forms a widely accepted technology and can be used at home by non-professionals. By modulating for example, the oxygen concentration supplied to the patient or the capillary blood temperature under the SpO2 probe the partial carbon dioxide pressure can in principle be derived from the oxygen saturation signal. This is based on the Bohr-Haldane effect: the Oxygen-Hemoglobin Dissociation Curve (OHDC) - the relation between the partial oxygen pressure and the oxygenation - is a function of the pH and thus of the PaCO2.

Study objective

To study the effect (signal, accuracy) of varying CO2 blood gas levels as well as different capillary blood temperatures on the SpO2 sensor signal. From the data obtained in this study the feasibility to derive the arterial CO2 value at 0.3 kPa accuracy from a modulation of either the capillary blood temperature or the inspired gas mixture (under well-controlled conditions) can be determined.

Study design

prospective, open, convenience sample of patients who have an operative indication voor non-cardiac vascular disease.

Intervention

A "formal"apnoe test, such is common practice during determination of brain death (i.e. 4-6 L/min of oxygen in the endotracheal tube, while the PaCO2 is allowed to rise) will be performed twice. veneus and aretrial blood gassen wil be used to monitor and as data. Additional bloodgasses will be performed during the reopenning of the vasculature (pH changes dur to revascularisation) and during the final phase of anesthesia (some acculmutaion of CO2 as spontanneous ventilation returns.

Study burden and risks

The additional risks due to an apnea test are negligible. The limits between which PaCO2 and SpO2 will be varied conform to good clinical practice. During the total procedure, the anesthesiologist takes the responsibility for the test and the anesthesia status of the patient. The anesthesiologist assistant will not take part in the test procedure, and is therefore fully dedicated to the patient. The presence of both the anesthesiologist and anesthesiologist assistant during the tests provides an extra level of security

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

have an indication for elective vascular surgery, under general anesthesia
ASA 1-3
accept informed consent
availablity of study team

Exclusion criteria

known to be pregnant
ASA 4, or urgent surgery
under the age of 18
known to have cancer or an other life-threatening co-morbidity

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2011
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
CCMO	NL36766.008.11