Impact of Melanin Content on Pulse Oximetry Accuracy

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Ethical review	Approved WMO
Status	Completed
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON56576

Source
ToetsingOnline

Brief title
IMPCA

Condition

- Respiratory tract infections

Synonym
Hypoxemia, occult hypoxemia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: SmartQare B.V.

Intervention

Keyword: Pulse oximetry, racial bias, Skin tone

Outcome measures

Primary outcome

the primary performance metric is ARMS, the root mean square of the difference between simultaneous paired measurements of SpO2 and SaO2 pooled across all measurements from all subjects.

Secondary outcome

- Determine whether there is a difference in ARMS obtained for the Fitzpatrick type III-VI to previously obtained measurements for Fitzpatrick type I-II.

- Determine if the rate of occult hypoxemia (SaO2 <= 88% while SpO2 >= 92%) differs significantly between Fitzpatrick skin type I-II vs III-VI for the ViQtor.

- Determine whether there is a difference in the occurrence of occult hypoxemia for the SmartQare ViQtor, Masimo Radical-7 and Philips Intellivue.

- Determine accuracy of ViQtor respiratory rate by comparing it to capnography verified respiratory rate from a reference device (Masimo ISA OR+).

- Determine accuracy of ViQtor pulse rate by comparing it to ECG verified heartrate from a reference device (Philips MX-850).

- Determine whether changes in cardiac output affect the hypoxic ventilatory response.

Study description

Background summary

Racial bias in pulse oximetry has been demonstrated in a number of retrospective studies. Occult hypoxemia is more prevalent in black patients and is related to poorer outcome. This is likely owing to the absence of black participants in diagnostic accuracy tests for pulse oximetry, which has resulted in the FDA mandating the inclusion of data from participants with dark skin in all pre-market studies. The inclusion of 15 % of participants with dark skin is probably insufficient to definitively determine the lack of racial bias. Equal distribution among the six Fitzpatrick skin tones and performance with ARMS < 4.0% would allow for definitively determine absence of racial bias.

Study objective

The primary objective is to evaluate the accuracy of the SpO2 measurements by the ViQtor compared to matched SaO2 measurements obtained during a hypoxic measurements to obtain the root mean square (ARMS) for a range of skin types defined by Fitzpatrick type I-VI

Study design

a validation study

Intervention

Hypoxia is induced to by administering a FiO2 of 0.06 to induce desaturation to SpO2 70% measured by a reference pulse-oximeter.

Study burden and risks

During the experiment oxygen desaturation will be induced by reducing FiO2 which results in desaturation to SpO2 70%. Hypoxia results in an increase in ventilation and is associated with euphoria, so called *happy hypoxia*, which is generally considered to be quite a pleasant experience. Additional oxygen can be administered in case of discomfort due to hyperventilation and will swiftly resolve any discomfort. The risk of inducing hypoxia is negligible since the experiments will only be performed in healthy volunteers who are able to increase cardiac out thereby maintaining adequate oxygenation by maintaining adequate oxygen flux to the tissues. To obtain arterial blood gasses to obtain SaO2 an arterial catheter is placed in the radial artery of the non-dominant arm. The total amount of blood sampled will not exceed 200 ml which will not any impact on the participant. Furthermore, all subjects are monitored using state of the art monitoring equipment comparable to that used in the operating rooms and intensive care units. The participants do not stand to benefit from participating in the study other than financial compensation for time spent in

our laboratory.

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

1.Healthy subjects aged 18 years and older.
2.Fitzpatrick skin type I-VI.
3.Subjects must be willing to give written informed consent for the trial and able to adhere to visit schedule.
4. Have no clinical or electrocardiographic signs of ischemic heart disease as determined by the Investigator with normal cardiac intervals appropriate for their gender. The Screening 12 lead ECG conduction intervals must be within gender specific normal range (e.g., QTcF <= 430 msec, PR interval <= 220 msec). ECGs are to be judged by the investigator or sub investigator as per

standardized procedures.
5. Vital sign measurements must be within the following ranges: (Individuals with values outside (or indicate lower or higher) of these ranges may be enrolled if clinically acceptable to the investigator and sponsor.
• body temperature, between 35.5°C and 37.5°C
• systolic blood pressure, 90 to 150 mmHg
• diastolic blood pressure, 40 to 95 mmHg
• pulse rate, 40 to 100 bpm

Exclusion criteria

1.Medical condition that would place the participant at risk during the hypoxic measurement or would interfere with the validity of measurements obtained as judged by the investigator
2.Pregnant or lactating
3.Abnormal Allen*s test (contra-indication arterial catheter placement)
4.Significant skin abnormalities on the upper arm (psoriasis, eczema, tattoos, scarring) that possibly interfere with photoplethysmography
5.Personal or familial history of cardiac arrhythmias (interfere with photoplethysmography)
6.Significant pulmonary disease which places the subject at increased risk during the hypoxic measurements
7.Use of anti-coagulants for any reason
8.Excessive facial hair preventing sealing of the occlusive face mask.
9. Participants who, in the opinion of the investigator, will not be able to participate optimally in the study.
10.Participants who are part of the study staff personnel or family members of the study staff personnel

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-02-2024
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	viQtor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-01-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL84986.000.23