

Understanding the influence of skin melanin content on the accuracy of pulse oximetry measurements

Submission date 18/01/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/02/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/02/2024	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Some studies have shown that there's a problem with how well pulse oximeters work, especially for people with darker skin. Pulse oximeters are those devices that clip onto your finger to measure oxygen levels in your blood. It turns out that these devices might not be as accurate for people with darker skin, and this could lead to worse health outcomes.

The issue seems to be because the studies used to make these devices didn't include enough people with dark skin. Because of this, the U.S. Food and Drug Administration (FDA) now requires new studies to include a significant number of participants with dark skin.

However, just having 15% of participants with dark skin might not be enough to really fix the problem. To make sure these devices are fair for everyone, the researchers suggest that they need to include people with different shades of skin tones and perform well for those with less than 3.5% error in measurements.

The main goal of this study is to check how well a specific pulse oximeter, called viQtor, measures oxygen levels compared to accurate SaO₂ measurements. This will help determine if viQtor is reliable for people with various skin tones.

Who can participate?

Healthy human volunteers, aged 18 years or older, evenly distributed over skin types Fitzpatrick I-II, III-IV and V-VI.

What does the study involve?

Researchers are deliberately causing a lack of oxygen in the body by giving a low concentration of oxygen (FiO₂ of 0.06). This is done to lower the oxygen saturation level in the blood to 70%, which is measured using a reference pulse oximeter.

The main thing they are looking at to assess how well everything is working is a metric called ARMS. This stands for the "root mean square," which is a way to find the average difference between the measurements of oxygen saturation taken at the same time from both the pulse oximeter (SpO₂) and a more accurate measurement (SaO₂). They collect this data from all participants in the study to get an overall picture of how well the method is performing.

What are the possible benefits and risks of participating?

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 output thereby maintaining adequate oxygenation and guaranteeing adequate oxygen flux to the tissues. To obtain arterial blood gases and 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 have any impact on the participant. Furthermore, all subjects are monitored using state-of-the-art monitoring equipment comparable to that used in 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.

Where is the study run from?

Leiden University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?

January 2024 to August 2024

Who is funding the study?

Leiden University Medical Center (Netherlands)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

P23.083

Study information

Scientific Title

Impact of melanin content on pulse oximetry accuracy

Acronym

IMPCA

Study objectives

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

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 14/01/2024, Medisch-Ethische Toetsingscommissie Leiden Den Haag Delft (Albinusdreef 2, Leiden, 2333 ZA, Netherlands; +31 (71) 526 3241; s.c.jansen@lumc.nl), ref: P23.083

Study design

Validation study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Laboratory

Study type(s)

Treatment, Safety

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Accuracy of the SpO₂ measurements by the viQtor pulse oximetry compared to matched SaO₂ measurements obtained during a hypoxic measurement in healthy volunteers

Interventions

The first visit or screening will include medical history and physical examination to determine suitability and determine the presence of inclusion and exclusion criteria. The second visit, the day of the experiment, the participant will be seated in a semi-supine position in a hospital bed. The participant will be connected to monitoring devices. Following application of local anesthesia an arterial catheter is placed in the radial artery in the non-dominant arm. A mask will be placed comfortably over the nose and mouth which is connected to the Leiden gasmixer via tubing. After acclimatization to the apparatus the FiO₂ (oxygen concentration in the gas mixture) will be decreased from 0.21 to 0.06 resulting in gradual desaturation to SpO₂ 70% on a reference pulse oximeter. Following stabilization of SpO₂ between 70-80% arterial samples will be drawn and time-stamped, FiO₂ will then be increased in order to achieve a SpO₂ of 80-90% and finally 90-100%. During a hypoxic measurement approximately 30-40 samples will be drawn requiring on average three hypoxic measurements. When the required amount of samples are obtained the measurements are discontinued the arterial catheter is removed and the participant will be observed to ensure vital signs are stable and the participant is fit to leave the facility. No specific dietary adjustments are required for the current protocol.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

ViQtor

Primary outcome measure

ARMS of SaO₂ and SpO₂ from paired samples obtained during hypoxia where SpO₂ 70-100% is measured by reference pulse oximeter. In accordance with FDA guidelines: "In premarket desaturation studies, 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 measures

Measured at a single timepoint when a steady plateau in saturation is reached during hypoxia:

1. Bias and ARMS for Fitzpatrick type I-II, type III-IV and V-VI measured using the Bland Altman method
2. Bias and ARMS for gender measured using the Bland Altman method
3. The rate of occult hypoxemia (SaO₂ ≤ 88% while SpO₂ ≥ 92%) for Fitzpatrick skin type I-II, III-IV and V-VI for ViQtor pulse oximetry
4. The occurrence of occult hypoxemia for the ViQtor, Masimo Radical-7 and Philips Intellivue pulse oximetry
5. The accuracy of viQtor respiratory rate compared to capnography-verified respiratory rate from a reference device (Masimo ISA OR+)
6. The accuracy of the viQtor pulse rate compared to ECG-based heart rate from a reference device (Philips MX-850)
7. Cardiac output effect on the hypoxic ventilatory response measured using the Edwards Hemisphere

Overall study start date

14/01/2024

Completion date

10/08/2024

Eligibility

Key inclusion criteria

1. 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 dose and 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)
 - 5.1. body temperature, between 35.5°C and 37.5°C
 - 5.2. systolic blood pressure, 90 to 150 mmHg
 - 5.3. diastolic blood pressure, 40 to 95 mmHg
 - 5.4. pulse rate, 40 to 100 bpm

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

99 Years

Sex

Both

Target number of participants

36

Key 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

Date of first enrolment

05/02/2024

Date of final enrolment

05/04/2024

Locations**Countries of recruitment**

Netherlands

Study participating centre

Leiden University Medical Center

Albinusdreef 2

Leiden

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

Website

<https://www.lumc.nl/?setlanguage=English&setcountry=en>

ROR

<https://ror.org/05xvt9f17>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Leids Universitair Medisch Centrum

Alternative Name(s)

Leiden University Medical Center, LUMC

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Netherlands

Results and Publications**Publication and dissemination plan**

Planned publication in a peer reviewed journal

Intention to publish date

05/10/2024

Individual participant data (IPD) sharing plan

Currently unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date