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

Submission date
18/01/2024

Recruitment status
No longer recruiting

Registration date
21/02/2024

Overall study status
Completed

Last Edited
21/02/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 out thereby maintaining adequate oxygenation and guaranteeing adequate oxygen flux to the tissues. To obtain arterial blood gasses 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?
1. Simone Jansen, s.c.jansen@lumc.nl
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Public, Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Validation study

Study type(s)
Treatment, Safety

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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ViQtor

Primary outcome(s)
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.”

Key secondary outcome(s)
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 Hemosphere

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

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
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Sponsor information

Organisation
Leiden University Medical Center

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 Leiden, LUMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

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