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EarMetrics®-Oximeter - a targeted oxygenation observation study

Submission date
16/07/2025

Recruitment status
No longer recruiting

Registration date
27/10/2025

Overall study status
Completed

Last Edited
16/06/2026

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will investigate the safety and performance of the EarMetrics®-Oximeter device for the calculation of blood oxygen levels. This pulse oximeter is intended to be placed in the ear canal to estimate blood oxygen levels. The advantage of the inner-ear canal is that the skin inside the ear does not contain any pigmentation (skin colour), and measuring blood oxygen levels from this part of the body is likely to provide more accurate measurements for people with darker skin. Other oximeters (for example, the finger pulse oximeter) are dependent on the level of skin pigment (melanin) and can be inaccurate when assessing oxygen levels for people with brown or black skin. This study aims to show that the EarMetrics®-Oximeter device can safely measure blood oxygen levels in comparison to the “gold-standard” method of measuring blood oxygen levels (SaO2), with acceptable accuracy. This will be done by measuring blood oxygen levels whilst gradually reducing the oxygen breathed (referred to as the controlled desaturation procedure).

Who can participate?
Healthy adult volunteers with a range of skin tones aged 18 to 55 years.

What does the study involve?
The study involves attending a one-off study visit at the University Hospitals Birmingham Clinical Research Facility. On arrival, the study doctor will discuss the study in detail with the volunteer and demonstrate the equipment to be used. The study doctor will also confirm the volunteer's health status by completing the Health Assessment Form. If the volunteer is eligible and wishes to continue, informed consent will be obtained. Female volunteers will need to provide a urine sample for the pregnancy test.
Before the controlled desaturation procedure (gradual reduction of the oxygen breathed), routine non-invasive equipment is applied to measure basic observations like blood pressure, heart rate and body oxygen levels (fingertip probe). The EarMetrics Oximeter device will be placed in the ear. A small plastic tube will be inserted into an artery (blood vessel) in your wrist. The area will be numbed before the local anaesthetic injection (lidocaine). The plastic tube in the artery will be connected with the monitor to observe the blood pressure throughout the procedure. A tight-fitting mask will be fitted over the volunteer's mouth and nose and adjusted for comfort and to minimise gaps between the mask and face. The mask will deliver different

levels of oxygen during the controlled desaturation procedure to temporarily reduce the blood oxygen levels in a controlled and stepwise manner. The plastic tube in the artery is used to collect the blood samples to be analysed for blood oxygen levels (SaO2). If the volunteers do not tolerate the reduced oxygen level, the desaturation process will be terminated, and the oxygen level will be restored by providing extra oxygen. Throughout the controlled saturation procedure, volunteers will be closely monitored by the trained clinical and nursing staff. Once all the required blood samples are taken and the oxygen levels restored, the tight-fitting mask and arterial cannula will be removed. Pressure to the cannula site will be applied to stop the bleeding. Before leaving the research facility, the study volunteer is asked to complete a post-procedure survey to describe their experience. The following day, the research staff member will follow up with the volunteer over the phone to confirm the wellbeing of the participant.

What are the possible benefits and risks of participating? There will be no direct medical benefits to participants at this stage in the development of the EarMetrics®-Oximeter. In the future, the EarMetrics®-Oximeter may improve the monitoring of oxygen levels of patients in health care settings. There are potential risks to participation, although participants will always be under close and continuous medical supervision in a dedicated research facility. Overall, the risks are low. Over the last 30 years public and private hypoxia laboratories have conducted more than 10,000 hypoxia studies with zero serious adverse events from either the hypoxia procedure or the arterial lines. Based on these data the risk of even minor adverse events is less than 0.03 %.

Where is the study run from?
The University Hospitals Birmingham, UK.

When is the study starting and how long is it expected to run for?
October 2025 to September 2026.

Who is funding the study?
1. The Asthma+Lung UK, UK.
2. West Midlands Health Technology Innovation Accelerator, UK.

Who is the main contact?
Dr Nick Gompertz, info@earswitch.co.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
353410

Central Portfolio Management System (CPMS)
66894

Protocol serial number
ES026 1

Study information

Scientific Title
EarMetrics®-Oximeter - a targeted oxygenation observation study: a controlled desaturation study to establish the safety and performance of the EarMetrics®-Oximeter Validation Device

Acronym
EMO-TOS

Study objectives
Finger-clip pulse oximeters have been relied upon since the 1970s, yet research from as early as 1990 points to their potential inaccuracy for people with darker skin. The COVID-19 pandemic saw a resurgence of research in this area, and engineers are now testing ways to make finger-clip devices more accurate for people with darker skin – such as by swapping red light for green light. Yet, while adjusting finger-clip oximeters might address racial bias, looking at other sites entirely could offer another means of measurements. As it's unpigmented irrespective of skin colour, the ear canal presents a measurement site that could be less vulnerable to racial bias.

EarSwitch's in-ear oximetry device, the EarMetrics®-Oximeter Validation Device is aiming to be a medical device which performs reflectance photoplethysmography (PPG) as well as taking videographic and photographic images from the inner two-thirds of the ear canal (the bony ear-canal), to estimate the SpO2. As the bony ear-canal is unpigmented, it provides a measurement site that is likely to be less vulnerable to racial bias due to skin colour. The next steps in improving monitoring capabilities, is to calibrate and establish the performance of the device's pulse oximetry capabilities in establishing oxygen saturation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/03/2025, Cambridge East Research Ethics Committee (2 Redman Place, London, EC201JQ, United Kingdom; +44 (0)2071048181; CambridgeEast.REC@hra.nhs.uk), ref: 25/EE /0338

Primary study design

Observational

Study design
Comparative single-centre non-randomized study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
This study is a comparative, single-centre, non-randomised study with a minimum of 24 subjects. Each subject test is expected to take approximately 3-4 hours. The overall data collection process will occur over an estimated 24 separate days. The entire duration of the study is anticipated to be 3-4 months. The study will be conducted in the NIHR Birmingham Clinical Research Facility by a senior anaesthetic trainee with access to all emergency and resuscitation equipment and support staff.

The study will be conducted in healthy volunteers to ISO 14155:2020 and current NHS Health Research Authority rules. REC approved Participant Information sheets (PIS), Health Assessment Forms (HAF) and Informed Consent Forms will be provided. Subjects will have sufficient time to review the PIS and have all questions answered regarding their participation before consent, enrolment or conduct of study-specific procedures. As applicable, subjects will be told about any new information that might change their decision to participate.

Volunteers who have completed (signed and dated) the informed consent form and Health Assessment Form (HAF) and meet all of the inclusion criteria and none of the exclusion criteria (see below) will be enrolled in the study.

Volunteers do not need to undress for the study but will be asked to wear a short sleeved top. The procedure and all equipment will be demonstrated before use. They will be asked to lie in a comfortable head-up position on a standard hospital bed. 3 self-adhesive ECG electrodes, a non-invasive blood pressure cuff and a finger pulse oximeter will be attached. A set of baseline observations will be recorded breathing room air. One EarMetrics- Oximeter Validation Device (Earbud A or B, in either sizes small medium or large) will be placed in either the left or right ear and confirmed to be comfortable and generating an adequate image of the inner two-thirds of the ear and consistent waveform on the EarMetrics®-Oximeter display. After the EarMetrics-Oximeter Validation Device images and signal are confirmed and consistent, the controlled desaturation study can progress.

Using palpation or ultrasound the radial artery in the non-dominant or preferred wrist will be identified and an Allen’s test performed to confirm collateral blood flow. A small amount of 1% lidocaine will be injected under the skin and a standard 20G arterial cannula inserted (BD Floswitch). An arterial blood pressure transducer with integrated flush will be attached and correct intra-arterial placement confirmed.

A 1.5 ml baseline arterial blood gas will be taken and analysed on a reference CO-oximeter This will provide a haemoglobin level, exclude high levels of carboxyhaemoglobin or methaemoglobin, abnormal blood sugars, abnormal blood oxygen or carbon dioxide levels. The thorough review of this baseline arterial blood gas is to optimise participant safety.

Following a careful demonstration, a close fitting anaesthetic facemask with harness will be attached to the face and the volunteer will breath controlled gas mixture through a standard anaesthetic breathing system and machine. Further 1.5 ml arterial blood gas samples will be taken as each stable plateau of required saturation is reached, as per the validated finger probe oximeter.

Data will be collected by EarMetrics-Oximeter validation device onto onto the EarMetrics-Oximeter Validation Device SD card. The SpO2 accuracy of the test device will be evaluated over the oxygen saturation range between 70-100% by comparison with arterial blood gas saturations (SaO2).

Intervention Type
Other

Primary outcome(s)
1. Performance: validation of the EarMetrics®-Oximeter Validation Device's ability to evaluate the SpO2 in comparison to the “gold-standard” measurement of blood SaO2 by a co-oximeter, measured using a sequence of arterial blood gas samples taken as per a one-off standardised desaturation procedure.
2. Safety: safety of the EarMetrics®-Oximeter pulse oximeter measured through the monitoring of device-related adverse events. Adverse events were monitored throughout the desaturation procedure and one day after the procedure.

Key secondary outcome(s)
Usability, utility, positioning and fit and comfort of the device are measured with a one-off non-validated participant survey completed after the desaturation procedure

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Age 18 to 55 years
2. Willing and capacity to provide written informed consent
3. Healthy adult subjects (American Society of Anesthesiologists [ASA] 1)
4. Non-smoker
5. Willing and able to comply with study procedures and duration

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Smokers or individuals exposed to high levels of carbon monoxide
2. Compromised circulation, injury, or physical malfunction of the sensor sites which would limit the ability to test sites needed for the study.
3. Morbidly obese (defined as BMI >39.5 kg/m²) or significantly underweight (BMI <18 kg/m²)
4. Female subjects that are actively trying to get pregnant or are pregnant. N.B. All female participants will need to complete a pregnancy test
5. Female subjects unwilling to perform a urinary pregnancy test.
6. Unwillingness or inability to remove coloured nail polish or nail attachments from test digits (relevant for reference pulse oximeter) or to have medical monitoring attached.
7. Known health conditions disclosed on Health Assessment Form which mean that participant is not healthy
8. Allergy to lidocaine
9. Allergy to adhesives used in medical dressings or tapes or materials used in EarMetrics earpieces (Please refer to the Investigators Brochure ES026 1 0850)
10. Diagnoses- past and present: Ear wax impaction, chronic otitis externa, acute otitis media, cholesteatoma, tympanic membrane perforation
11. Symptoms of ear infection or inflammation as indicated by in-ear pain, discharge and/or irritation.
12. Use of hearing aids
13. Enrolment in any other clinical investigation (co-enrolment)

Date of first enrolment
14/10/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Clinical Research Facility
Queen Elizabeth Hospital
Edgbaston
Birmingham

England
B15 2TH

Sponsor information

Organisation
EarSwitch Ltd

Funder(s)

Funder type
Charity

Funder Name
Asthma and Lung UK

Alternative Name(s)
asthmalunguk, Asthma + Lung UK, Asthma UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository with data divided between EarSwitch and the Trail site.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.8	01/08/2025	14/10/2025	No	Yes