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# First-in-man evaluation of a rapid, real-time, arterial oxygen sensor in the critically ill

**Submission date**
16/03/2023

**Recruitment status**
No longer recruiting

**Registration date**
11/04/2023

**Overall study status**
Completed

**Last Edited**
11/04/2023

**Condition category**
Respiratory

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

## Plain English summary of protocol

Background and study aims
More than 200,000 patients are admitted to ICUs in the UK each year. Among these, 10% develop acute respiratory distress syndrome (ARDS), a life-threatening condition of severe respiratory failure which is associated with long-term illness in survivors. Often, ARDS requires the use of invasive mechanical ventilation in order to maintain adequate gas exchange, but mechanical ventilation can further injure damaged lungs if inappropriately used. A bedside reference method is needed to monitor ventilator-induced lung injury (VILI) and to select the most appropriate mechanical ventilatory settings. A novel approach might be to measure within-breath changes in the arterial partial pressure of oxygen (PaO2).
Detecting PaO2 oscillations at the bedside and tracking their changes at varying ventilatory settings may open a new field of research with highly relevant clinical implications for mechanically ventilated ARDS patients. The main aim of this study is to assess the feasibility of continuous measurement of PaO2 oscillations with a real-time, intra-arterial, fibre-optic sensor in patients with acute respiratory distress syndrome (ARDS) under mechanical ventilation.

Who can participate?
Mechanically ventilated ARDS patients aged 18 years and over

What does the study involve?
Patients will be equipped with the oxygen sensor and PaO2 is continuously measured and recorded (together with all other routinely monitored parameters) during standard clinical care with no intervention. Patients will remain in the study for as long as they are mechanically ventilated in controlled mode, so as to track changes in PaO2 oscillations. The sensor will be removed and changed with a new one every 24 hours to ensure signal quality. No follow-up procedure is planned for this study.

What are the possible benefits and risks of participating?
There are no direct benefits for participants, as this study is limited to observing blood oxygen during standard clinical care. However, it may have the potential to transform the care of ARDS patients worldwide.
Only minor risks might be associated with this study: the oxygen sensor has been assessed and confirmed to be suitable for its intended use in humans, with no or minimal expected risk of

immunological reactions. It has also been proven that its contact with blood does not cause clotting for at least 24 hours, so the researchers do not expect this to occur. Insertion of the sensor into the blood vessel catheter will be performed by members of the research team who are experienced clinicians; they will use sterile equipment, so risks of infections will be minimal. The blood pressure signal from the blood vessel catheter where the sensor will be sited is normally unaltered by the presence of the sensor, and even in the unlikely event of signal disturbances, there will be several other ways to monitor blood pressure (e.g., with a brachial blood pressure cuff). The researchers will continuously monitor patients throughout the study period to identify adverse changes, and any unexpected event will lead them to immediately interrupt the study and remove the sensor.

Where is the study run from?
Guy's and St Thomas' NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to July 2024

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Prof Andrew Farmery, andrew.farmery@nda.ox.ac.uk

# Contact information

### Type(s)
Principal Investigator

### Contact name
Prof Andrew Farmery

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
321576

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers
IRAS 321576

# Study information

### Scientific Title
First-in-man evaluation of a fibre optic sensor to monitor ventilatory oscillations in the arterial partial pressure of oxygen in real-time: a feasibility study in patients with the acute respiratory distress syndrome

### Acronym
FIbreOxyll

### Study objectives
In patients with acute respiratory distress syndrome (ARDS), monitoring oscillations in the arterial partial pressure of oxygen (PaO2) with a new, real-time, fibre-optic sensor is feasible. Feasibility is defined as the capability of the sensor to detect changes in oscillations induced by an event of routine clinical care. Specifically, it is hypothesised that a real-time, fibre-optic oxygen sensor can detect changes in PaO2 oscillations induced by a change in positive end expiratory pressure (PEEP) performed for clinical reasons to calculate the recruitment to inflation (R/I) ratio.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approval pending, Research Governance, Ethics & Assurance Team of the University of Oxford (Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, UK)

### Study design
Single-centre observational prospective cohort study

### Primary study design
Observational

### Secondary study design
Cohort study

### Study setting(s)
Hospital

### Study type(s)
Other

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

## Health condition(s) or problem(s) studied
Critically ill, mechanically ventilated patients with acute respiratory distress syndrome (ARDS)

## Interventions
Mechanically ventilated ARDS patients will be equipped with a real-time oxygen sensor inserted in an indwelling arterial catheter (already in place for clinical reasons) and connected to a monitoring system. The protocol consists of continuously observing and recording the arterial partial pressure of oxygen (PaO2) signal displayed by the monitor during standard clinical care, with no intervention. Patients will remain in the study for as long as mechanically ventilated in controlled mode. The sensor will be removed and changed with a new one every 24 hours to ensure signal quality.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Device: Oxygen fibre sensor, Oxford Optronix; monitoring system: Oxylite Pro EL91037, Oxford Optronix

## Primary outcome measure
The amplitude of PaO2 oscillations (peak to trough difference) is measured with the real-time oxygen sensor at the two levels of positive end expiratory pressure (PEEP 15 vs 5 cmH2O) required to calculate the recruitment to inflation (R/I) ratio

## Secondary outcome measures
The phase of PaO2 oscillations (phase angle between PaO2 oscillations and airway pressure curve) is measured offline by superimposing the PaO2 and airway pressure signals (respectively from the oxygen sensor and the ventilator) obtained at the two levels of positive end expiratory pressure (PEEP 15 vs 5 cmH2O) required to calculate the recruitment to inflation (R/I) ratio.

The amplitude and phase of PaO2 oscillations (measured as above) and other routinely monitored variables (see below*) will be assessed during the following manoeuvres if and when the attending physician considers that they might be beneficial for the patient:

1. At the two levels of positive end expiratory pressure (PEEP 15 vs 5 cmH2O) required to assess the recruitment to inflation (R/I) ratio.
2. At the two levels of positive end expiratory pressure (PEEP 5 vs 45 cmH2O) required to measure static lung recruitability during lung computed tomography scan (CT scan).
3. Before and after a change in body position (e.g., from supine to prone, and/or from prone to supine)
4. Before and after any change in ventilatory or extracorporeal support settings
5. During any manoeuvre performed to assess lung mechanics (e.g., inspiratory/expiratory pause, static/dynamic pressure-volume loop)

*From the ventilator: airway pressures, flow, tidal volume (Vt), inspiratory to expiratory time ratio (I:E), respiratory system compliance, lung stress and strain, airway opening pressure; from the extracorporeal membrane oxygenator if present: extracorporeal sweep gas flow (SGF), blood flow, fraction of extracorporeal oxygen (FdO2)); from the analysis of CT scan if performed:

functional residual capacity (FRC)), well-aerated/poorly aerated/non-aerated/hyperinflated lung volume; from the electrical impedence tomography (EIT) if present: lung impedance; from the ICU monitor: peripheral oxygen saturation (SpO2), end tidal carbon dioxide pressure (EtCO2), heart rate, arterial and venous blood pressures, cardiac output (if advanced monitoring available); from the arterial and central venous lines: arterial and venous blood gases if considered beneficial by the attending physician.

### Overall study start date
01/01/2019

### Completion date
31/07/2024

## Eligibility

### Key inclusion criteria
1. Adult patient ≥18 years
2. Mechanically ventilated and sedated in controlled ventilation
3. PaO2 to inspired oxygen fraction (FiO2) ratio (P/F) ≤26.6 kPa
4. Indwelling arterial catheter
5. Planned for a PEEP change from 15 to 5 cmH2O to measure the recruitment to inflation ratio (R/I ratio)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### Key exclusion criteria
1. Pregnancy
2. Respiratory failure due to acute heart failure
3. Severe hemodynamic instability defined as either continuous infusion of noradrenaline (NA) at a rate >0.5 micrograms/kg/minute, or the presence of at least one cardiac support device: intra-aortic balloon pump (IABP), Impella, Veno-arterial extra-corporeal membrane oxygenation (VA-ECMO)
4. Tidal volume (Vt) <3 ml/kg of body weight
5. Respiratory rate (RR) >30 breaths/minute
6. Peripheral oxygen saturation (SpO2) <90%

### Date of first enrolment

01/06/2023

**Date of final enrolment**
31/12/2023

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**St Thomas Hospital**
Westminster Bridge Road
London
United Kingdom
SE17EH

# Sponsor information

**Organisation**
University of Oxford

**Sponsor details**
Research Governance, Ethics and Assurance
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**Sponsor type**
University/education

**Website**
http://www.ox.ac.uk/

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care Research (NIHR200681)

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
The results of this study will be disseminated in peer-reviewed scientific journals, presented at conferences, and published on our website (https://www.ndcn.ox.ac.uk/news).

The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. The authors will acknowledge that the study was funded by NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. All investigators will have free access to raw data. Depending on the results, the work could be submitted to any of the following:
1. American Journal of Respiratory and Critical Care Medicine
2. European Respiratory Journal
3. Intensive Care Medicine
4. Critical Care Medicine
5. Critical Care
6. Intensive Care Medicine Experimental
7. Journal of Physiology
8. Journal of Applied Physiology
9. Experimental Physiology

**Intention to publish date**
31/07/2025

**Individual participant data (IPD) sharing plan**

The dataset generated during and/or analysed during the current study are/will be available upon request from Prof. Andrew Farmery (andrew.farmery@nda.ox.ac.uk)

## IPD sharing plan summary

Available on request