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Testing the effects of low levels of blood oxygen and movement of the accuracy of portable vital signs monitors

Submission date 28/05/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/06/2019	**Overall study status** Completed	
Last Edited 19/07/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Despite best efforts, there is continuing evidence that a proportion of hospitalised patients worsen, sometimes due to reversible causes. Failure to identify and act on indicators of worsening acute illness in hospital wards is a problem that has been known for more than 10 years. “Track and Trigger” scoring systems are used in practice to check “standard" vital signs. These are pulse rate, respiratory rate, blood pressure, oxygen level and temperature. These are taken at timed intervals based on a protocol which is selected based on the clinical condition of the patient. Intermittent application of vital sign monitoring devices can be time-consuming. As a result the correct frequency of observations is often missed. Continuous vital sign monitoring within the ward environment is not currently workable, but it’s believed to increase the timely detection of patient deterioration. Wearable ambulatory monitoring systems (AMS) may provide an alternative continuous monitoring system which may improve the early detection of irregular physical and biological parameters. AMS would allow patients to be more mobile and have less discomfort. The aim of this study is to test whether the devices will be able to give correct readings and be suitable for clinical use. This is to ensure that AMS kits give accurate and reliable readings. To achieve this these kits need to be rigorously tested on 30 healthy volunteers.

Who can participate?
Men and women aged 18 or over and in generally good health

What does the study involve?
Participants will be attached to a standard hospital monitor and the portable monitors being tested. A small tube will be inserted into their radial artery (called an arterial line). This will allow the study doctor to take blood samples during the study. Participants will be asked to follow a series of movements designed to mimic those commonly made by patients in hospital, such as drinking, standing and reading. They will then be asked to wear a tight-fitting mask attached to a machine. This will gradually lower the amount of oxygen in their blood. Throughout the study, blood samples will be taken from the arterial line to measure blood oxygen levels. At the end of the study the mask will be removed, oxygen levels returned to normal and the arterial line will be removed.

What are the possible benefits and risks of participating?
The risks involved in participation in this study are few. The procedures to be carried out in this study are generally well tolerated. The member of the research team carrying out these procedures will have done them a great number of times before and be technically skilled so as to minimise discomfort. Although rare, there is always a risk of minimal complications during arterial line placement and decreased oxygen exposure, for example bruising and fainting. Other rare complications of the arterial line can include temporary vascular occlusion, thrombosis, ischemia, hematoma formation, and local and catheter-related infection, sepsis and nerve damage. If symptoms become unpleasant, the testing will be stopped. These side effects should rapidly reverse following breathing normal room air.

Where is the study run from?
John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2018 to March 2022

Who is funding the study?
NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
Dr Sarah Vollam
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
251711

Study information

Scientific Title
Virtual HDU: hypoxia study. Accuracy and validity testing of ambulatory monitoring system

Acronym
vHDU-Hypoxia

Study objectives
The primary objective of the study is to determine the specificity and sensitivity of commercially available ambulatory vital-sign monitoring equipment for detection of hypoxia. This phase of the study will test the ambulatory monitoring equipment on healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2019, East of Scotland Research Ethics Service REC 2 (Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee DD1 9SY, Tel: +44 (0)1382 383878; Email: eosres.tayside@nhs.net), ref: 19/ES/0008

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Vital sign monitoring

Interventions
Participants will visit the designated research facility for the study visit. On arrival, participants will be assessed for their suitability for the study. An arterial line will be inserted into their radial artery. They will be connected to a standard hospital monitor and the ambulatory monitors being tested. Throughout the study, data from all monitors will be recorded. In the movement phase, participants will follow a series of protocolised movements designed to replicate usual patient movements. Arterial blood samples will be taken at the end of each movement. During the hypoxia phase, participants will lie on a bed with a tight face mask delivering reduced levels of inhaled oxygen. Their blood oxygen levels will be monitored and arterial blood gases taken at intervals as their oxygen saturations decrease. Throughout the procedures, an anaesthetist will be present and their vital signs closely monitored for safety purposes. After the hypoxia phase, their blood oxygen levels will be normalised and the arterial line removed. They will remain with the study team until deemed to have recovered sufficiently to leave the research facility.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Specificity and sensitivity of currently available ambulatory vital-sign monitors will be assessed by comparing continuous oxygen saturation, pulse rate and breathing rate data from each ambulatory monitor with arterial blood oxygen saturation measured through blood gas analysis, respiratory rate derived from capnography and pulse rate derived from ‘usual care’ hospital grade pulse oximetry monitoring. Arterial oxygen saturation will be measured at incremental drops in SpO2, up to 80%. Respiratory rate and pulse rate will be measured continuously throughout testing.

Key secondary outcome(s))
The effects of movement on data acquisition by currently available ambulatory vital-sign monitors will be assessed by comparing continuous oxygen saturation, pulse rate and breathing rate data from each ambulatory monitor with arterial blood oxygen saturation measured through blood gas analysis, respiratory rate derived from capnography and pulse rate derived from ‘usual care’ hospital grade pulse oximetry monitoring. Arterial oxygen saturation will be measured after each movement is completed. Respiratory rate and pulse rate will be measured continuously throughout testing.

Completion date
01/03/2022

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Men and women aged 18 or over and in generally good health

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
29

Key exclusion criteria
1. Allergies to adhesive dressings (such as bio-occlusive dressings or micropore) or local anesthesic (e.g. Lidocaine)
2. Intra-cardiac device (e.g. Permanent pacemaker) or previous wrist arterial line
3. Epilepsy
4. Angina, congenital heart disease or history of severe cardiopulmonary disease
5. History of anaemia (reported in the pre-screening telephone call) or Hb below 100 g/l on first test
6. Resting hypoxaemia (SpO2 <94%) or significant cardiopulmonary disease rendering exposure to alveolar hypoxia unsafe, as determined by the research physician
7. Pregnancy or breastfeeding
8. Clotting disorders and use of antiplatelet or anticoagulant medication (such as Aspirin)
9. Claustrophobia precluding spell in the hypoxic exposure

Date of first enrolment
18/06/2019

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Critical Care Research Group
Kadoorie Centre
Headley Way
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR

https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Oxford Biomedical Research Centre

Results and Publications

Individual participant data (IPD) sharing plan
De-identified data will be held with the University of Oxford electronic archive for 5 years after the end of the study. Datasets will be large and focused on validation of monitor outputs. However, de-identified datasets may be made available to researchers on written request to the PI (Dr Peter Watkinson: peter.watkinson@ndcn.ox.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2021	21/09/2021	Yes	No
Results article		15/02/2022	16/02/2022	Yes	No
Protocol article		12/01/2020	19/07/2023	Yes	No
HRA research summary			28/06/2023	No	No