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Continuous vital signs monitoring in healthy volunteers undergoing a COVID-19 challenge trial

Submission date
13/09/2022

Recruitment status
Recruiting

Registration date
16/09/2022

Overall study status
Ongoing

Last Edited
02/08/2024

Condition category
Infections and Infestations

[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
Currently, for nurses to watch vital signs closely, namely heart rate, respiratory rate, blood pressure, temperature and oxygen saturation, participants are either attached to a static machine by the participant's bedside using wires, or staff visit the participant every few hours to measure these vital signs using a portable wired machine. It is now possible to closely monitor participants using small devices which attach to the wrist, finger or chest. These devices allow nursing staff to continually watch vital signs data from these participants when they are away from their bedside. These machines are also wireless and portable, so they do not stop participants from moving around, which is important for recovery, and are comfortable to wear. In past years, researchers have tested these devices and developed a system to allow the clinical staff to see the continuous vital signs. Although a lot more is now known about the physiological impact of COVID-19, there is still a lack of research on the trajectory of vital signs for participants with this new condition. This system offers an opportunity to examine the patterns of vital signs both before and after inoculation with the virus. The aim of this study is to collect preliminary continuous vital sign data to investigate the feasibility of using these wearables to monitor and detect vital sign variation. In this initial study the researchers will only be collecting and analysing data from the COV-CHIM01 trial participants and the system will not be actively used for real-time monitoring.

Who can participate?
Participants must be aged 18 years or over and participating in the COV-CHIM01 trial

What does the study involve?
Those who agree to take part will be asked to wear two devices from Day -1 to Day 12 of their stay. Between them, these devices will record heart rate, respiratory rate and blood pressure. Although participants will be encouraged to wear these as often as possible, they can remove one or more devices temporarily, or choose to remove the system completely at any time. Participants will be asked to log the times when devices are removed and complete a questionnaire about how comfortable the devices were. As part of the COV-CHIM01 challenge study, the study team will measure participants' vital signs four times daily (heart rate, blood

pressure, oxygen saturation levels, breathing rate, and temperature) and will have daily COVID-19 swabs. These measurements will be compared with measurements taken by the two wearable devices. They will also be used to interpret the results depending on whether or not participants develop a COVID-19 infection.

What are the possible benefits and risks of participating?
There is no direct benefit from taking part in this study, however, participation will contribute to current evidence that will support further research on wearable ambulatory monitoring systems and a better understanding of vital sign trajectories before and after infection.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2022 to January 2028

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

Who is the main contact?
Prof. Peter Watkinson, rachel.henning@ndcn.ox.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Peter Watkinson

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
v3.0

Study information

Scientific Title
The virtual High Dependency Unit (vHDU) Challenge study: continuous vital signs monitoring in COVID-19 challenge participants

Acronym
vHDU-CS

Study objectives
To determine the feasibility of using wearable monitors to examine patterns of vital signs, before and after inoculation with the SARS-CoV-2 virus, within a medical research facility.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/09/2022, Medical Sciences Interdivisional Research Ethics Committee (Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, UK; +44 (0)1865 616575;
ethics@medsci.ox.ac.uk), ref: R80395/RE001

Study design
Single-centre observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The study will be conducted in the Clinical Research Facility at the Churchill Hospital in Oxford. The COV-CHIM01 trial participants (also the study population) are admitted 2 days prior to exposure to the SARS-CoV-2 virus. The virus exposure will be entirely managed by the COV-CHIM01 trial team.

Informed consent will be taken from willing participants after they are admitted to the Clinical Research Facility, but before the exposure to the virus. Following this, recruited participants will then have the VitalPatch (adhesive chest patch collecting heart rate and respiratory rate) and

Aktiia (wrist-worn unit collecting blood pressure) devices attached and will be instructed in their use by a member of the research team. Baseline blood pressure and temperature will be recorded by the research team in order to calibrate the wearable devices.

Recruited participants will be encouraged to wear the two devices (as tolerated) as much as possible including during sleep, from Day -1 of the COV-CHIM01 study (the day before inoculation) to Day 12.

The VitalPatch can be worn continuously, but participants will need to remove the Aktiia for showering, during which time the device can be placed on charge. This will be clearly discussed during the initial consent and specified in the Participant Information Sheet.

They will be visited on Day 6 of their quarantine period by a member of the research team, who will supervise the replacement of the VitalPatch and check the Aktiia device. During this visit participants will be asked to complete a wearability questionnaire.

On Day 12 of their quarantine period they will be visited again and the devices will be removed.

Participants who would prefer to wear only one of either the VitalPatch or the Aktiia will still be included in the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VitalPatch, Aktiia

Primary outcome(s)
The feasibility of early detection of COVID-19 infection using data collected by wearable devices and the measured variation in vital signs from continuous monitoring during the course of the study (up to Day 12)

Key secondary outcome(s))
1. Demographic data collected using a questionnaire at the start of the study
2. Wearability measured using a questionnaire on Day 6 of the study
3. Heart rate, respiratory rate, blood pressure, oxygen saturation, temperature data and infection data collected by the COV-CHIM01 study team at regular intervals based on Challenge protocol
4. Accelerometer data, heart rate and respiratory rate variability data from the wearable device (VitalPatch) monitored continuously during the course of the study (up to Day 12)

Completion date
01/01/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/08/2024:

1. Participation in the COV-CHIM01/COV-HIC001/COV-CHIM02 study
2. Participant is willing and able to give informed consent for participation in this study
3. Aged 18 years or over

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Previous inclusion criteria:

1. Participation in the COV-CHIM01 study
2. Participant is willing and able to give informed consent for participation in this study
3. Aged 18 years or over

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
All

Key exclusion criteria
1. Intra-cardiac device
2. Known history of cardiac arrhythmias
3. Allergy to adhesives

Date of first enrolment
20/09/2022

Date of final enrolment
01/09/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Oxford Clinical Research Facility
Churchill Hospital
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

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 are not expected to be made available as the data from the wearable devices is linked to another study. In the ethics

application this was extensively discussed and it was decided that the dataset will be held in a secure setting behind two doors and restricted access within Kadoorie Centre for Critical Care Research and Education and Institute of Biomedical Engineering secure server.

IPD sharing plan summary

Not expected to be made available