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Virtual HDU Phase 3: wireless vital sign monitoring system testing on a surgical ward

Submission date 10/05/2019	**Recruitment status** Suspended	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 14/06/2019	**Overall study status** Completed	
Last Edited 31/03/2020	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Hospital patients have their vital signs measured regularly. If they are very ill they may need to have them measured continuously. Current monitors are bulky or awkward. This can prevent them from moving and walking enough to help them get better. The Virtual HDU study is aiming to prevent patients from needing this type of monitoring unnecessarily. There are now small wireless vital sign monitors available. In the future we want to put these on hospital patients who are ill but, not ill enough to need standard wired monitors. The monitors may pick up when a patients vitals worsen. It will alert the nurses or doctors to check them and they may give them the treatment they need earlier. This could improve their recovery and could reduce the length of their hospital stay.

Who can participate?
Healthy clinical staff volunteers.

What does the study involve?
This study, Phase 3, involves testing different monitors on a NHS hospital ward to see how they work. This includes checking if the wireless signal is affected by the wards layout. We will test if the monitors are comfortable to wear and easy to use. this will then enable the refinement of the technology before patient testing. They will each wear a monitor for the duration of their shift, when appropriate. They will then complete a questionnaire about wearing the monitor.

What are the possible benefits and risks of participating?
No benefits or risks to participating.

Where is the study run from?
The study will be run by the Critical Care Research Group at the Kadoorie Centre for Critical Care Research and Education.

When is the study starting and how long is it expected to run for?
The study started in April 2019 and will run until October 2021 (updated 20/11/2019, previously: August 2019)

Who is funding the study?
This study is funded by the NIHR Oxford Biomedical Research Centre.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor (CTRG) and Research and Development ref: 13976

Study information

Scientific Title
Virtual HDU Phase 3: locational testing of ambulatory monitoring systems on a surgical ward

Acronym
Virtual HDU Phase 3

Study objectives
True continuous vital sign monitoring within the ward environment is not currently feasible due to limitations in vital sign monitoring technology but, is commonly believed to increase the timely detection of patient deterioration. Wearable monitors may provide an alternative continuous monitoring system, affording patients more mobility, less discomfort, reduce nursing time and improve the early detection of abnormal physiological parameters. Barriers to the successful implementation of these wearable devices are reliability, efficiency and data processing systems.

This study aims to demonstrate and test robust a wearable monitoring system with good reliability and reliability, but also be acceptable to end-users of the system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2019, Medical Sciences Interdivisional Research Ethics Committee, University of Oxford (Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD; +44(0) 1865 616577; +44(0)1865 280467; ethics@medsci.ox.ac.uk), ref: R61573/RE001.

Study design
Observational single-site mixed methods study

Primary study design
Observational

Secondary study design
Mixed methods 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
Healthy volunteers

Interventions
This study has been designed to optimise ambulatory monitoring systems to provide reliable continuous data recording in a clinical setting. This will be done during several rounds of testing and troubleshooting, to optimise the systems being tested for clinical use.

Healthy staff volunteers will wear the ambulatory monitor(s) around the target ward for up to the length of a working shift (up to 12 hours). They will wear up to three different combinations of ambulatory monitor. The participants can remove the monitor when needed to undertake direct patient care.

Information regarding the proprtion of time each vital sign parameter is recored versus the time the device was worn. The availability of data collected (via bluetooth and Wi-Fi) will be analysed. The data collection system (software and hardware) will be tested and analysed to detect and troubleshoot and fix errors and improve reliability.

Participants will be asked to complete a questionnaire, rating the user experience of the ambulatory monitors. Study is complete once all participants have worn all of the monitors and completed all questionnaires. There will be no further follow-up.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
N/A

Primary outcome measure
The proportion of time each vital sign parameter (heart rate, SPO2 and breathing rate) is recorded versus time the device is worn.

Secondary outcome measures
1. The frequency and duration of data drop-out for each vital sign parameter.
2. The waveform quality of each vital sign parameter.
3. The wear-ability of the device is measured using questionnaires after each time an ambulatory monitor wear session has ended.
4. The availability of data over the 12 hour period, log of issues and crashes.
5. Duration of battery is measured as life from full charge to battery drain.

Overall study start date
01/05/2018

Completion date
05/10/2021

Eligibility

Key inclusion criteria
1. Staff working for the Oxford University Hospitals NHS Foundation Trust, in the designated area.
2. Willing and able to give informed consent for the study.
3. Aged 18 or over
4. In good health.

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Allergies to adhesives dressings or metals e.g. Nickel.
2. Intra-cardiac device e.g. permanent pacemaker (only applicable to the chest patch monitor).

Date of first enrolment
17/06/2019

Date of final enrolment
05/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way,
Headington
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OX3 9DU

Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Results and Publications

Publication and dissemination plan
It is anticipated that the study outcome will be used to inform the design of future studies and in the application process for future research.
The project outcome may be written up for peer-reviewed publication with the possibility of being presented in conferences.
The results may be shared internally within the department/university.

We will offer to contact any participants who express an interest in the results of the project.

Intention to publish date
05/10/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date