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Post-Intensive Care Risk-adjusted Alerting and Monitoring (PICRAM Phase 2)

Submission date
20/09/2012

Recruitment status
No longer recruiting

Registration date
06/11/2012

Overall study status
Completed

Last Edited
15/04/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
To help doctors and nurses recognise when patients are becoming unwell, they are monitored in hospital by an Early Warning System called Track & Trigger. Each time clinical measurements (for example pulse, blood pressure, temperature and the bodys oxygen levels) are recorded, they are compared to a scale and given a number that represents the position on the scale. If the number is too high, the nurse at the bedside will respond by asking for help from a doctor or more senior nurse. Everyone is compared against the same scale and we do not know if this is the best way to monitor patients during their hospital stay. This study is designed to investigate whether it is possible to create a personalised monitoring programme for patients who are discharged from the Intensive Care Unit.
The aim of the study is to link information from a patients stay in the intensive care unit with measurements taken during their hospital stay after discharge from intensive care. We will use this information to programme an automatic alerting calculation that will be different for each patient. We want to test whether this new system will improve nurses and doctors abilities to watch over patients and if it might also alert them earlier to a patient who may be in need of more treatment, a different type of care, or more or less monitoring.

Who can participate?
Patients who are being discharged from the intensive care units at the Oxford University Hospitals NHS Trust and the Royal Berkshire NHS Foundation Trust.

What does the study involve?
Before patients leave the intensive care unit, or shortly after they arrival on their new ward, the study monitoring equipment will be attached to them. This involves attaching some sticky dots to their chest which will connect leads from the patient to the monitor so that their heart rate can be recorded. Patients will also be asked to wear a device that will measure the levels of oxygen in their blood.
Patients in the study will be visited by research nurses once or twice each day while they are wearing the monitoring equipment. The nurses will check that it is recording correctly and that there are no problems. They will also look at the patients medical notes and will record information about them and the treatment they are given during their hospital stay. Patients will be asked to wear the monitor until they are discharged from hospital. However, if they are

still in hospital fourteen days after they have been discharged from the intensive care unit, we will remove the monitor.

What are the possible benefits and risks of participating?
This study may help us in the future to improve the standard of care for patients who are at risk of developing health problems after their stay in the intensive care unit. We hope that the information we collect from patients about their stay in hospital will allow us to treat future patients faster and perhaps save lives. There are no known risks associated with taking part in this trial.

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

When is the study starting and how long is it expected to run for?
The study started in October 2012 and is expected to end in September 2014. The first patient will be recruited before the end of 2012.

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Ms Julie Darbyshire
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
12730

Study information

Scientific Title
Post-Intensive Care Risk-adjusted Alerting and Monitoring - an observational study

Acronym
PICRAM 2

Study objectives
Patients discharged from intensive care units (ICU) have a very high risk of subsequently deteriorating on hospital wards. PICRAM will develop ways of alerting clinicians to these deteriorations early. After ICU discharge, there is little information available about the normal course which patients vital signs follow if they are safely discharged from hospital. Using an ambulatory monitor we plan to continuously record vital signs from up to 500 patients who have spent more than three days in ICU from 2 hospitals (one teaching hospital Oxford University Hospitals NHS Trust one large district general hospital The Royal Berkshire NHS Trust). We will also recover vital signs from the 72 hours leading up to discharge from the ICU, (recorded in the standard clinical electronic database). These two sets of data will allow us to understand the patterns by which patient recovery is displayed in vital signs. We will develop ways by which clinicians can be alerted to patients who are not following these patterns of recovery, as these patients will be at greater risk of deterioration. Finally, we will recover data from the patients ICU stay. We have developed a large anonymised database from the standard clinical electronic databases of the two Intensive Care Units. We are using this to design tools to help clinicians recognise which patients are at risk of deterioration after discharge from intensive care. We will use data from the Intensive Care Unit stay of the patients whose vital signs we record after intensive care discharge to work out how best to merge the data from their time in Intensive Care with the vital signs recovery patterns to best identify patients who are deteriorating after ICU discharge.

The use of prolonged ambulatory vital sign monitoring in post-intensive care patients is relatively novel. We will therefore record patients views on the wearability of the system and data on the functionality of the system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford C Research Ethics Committee, 16/10/2012, ref: 12\SC\0357

Study design
Non-randomised observational cohort study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Critical care

Interventions

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Patients in the study will be visited by research nurses once or twice each day while they are wearing the monitoring equipment. The nurses will check that it is recording correctly and that there are no problems. They will also look at the patients medical notes and will record information about them and the treatment they are given during their hospital stay.
Patients will be asked to wear the monitor until they are discharged from hospital. However, if they are still in hospital fourteen days after they have been discharged from the intensive care unit, we will remove the monitor.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To collect a large dataset containing physiological data on patients

Key secondary outcome(s))
To demonstrate the feasibility of using commercially available

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Aged 16 years or above
3. Discharged from adult intensive care unit.
4. Male and female participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Patients discharged for palliative care
2. Patients whose anatomy, condition or prior surgery precludes the use of the wearable monitoring equipment
3. Patients who cannot understand written English and for whom no translator can be found
4. Patients not able to give informed consent due to diminished capacity

Date of first enrolment
01/10/2012

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust ref: HICF-0510-006

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available for research purpose upon specific request from the University of Oxford Critical Care Research Group (ccrg@ndcn.ox.ac.uk). The PICRAM dataset contains de-identified patient level data from several thousand patient records which were collated during the PICRAM project. The dataset is owned and controlled by the University of Oxford Critical Care Research Group Data Access Committee who review all requests for access on an individual basis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/04/2024	15/04/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes