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PROSPECT - Prognosis prediction after enhanced or critical care

Submission date
09/07/2025

Recruitment status
Recruiting

Registration date
14/08/2025

Overall study status
Ongoing

Last Edited
17/09/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Every year in the UK, around 14,000 people die unexpectedly or need urgent care again after being discharged from an Intensive Care Unit (ICU). Many others are readmitted to hospital within three months. This study wants to find out if using extra electronic health information—like wearable monitors—can help healthcare teams spot which patients are most at risk of getting worse after leaving ICU. The goal is to help staff decide who needs closer follow-up care.

Who can participate?
The study is open to adults aged 18 years and over who have spent more than 48 hours in an ICU and are ready to be discharged. Participants must be able to give informed consent, or have a representative who can do so on their behalf. People who have opted out of sharing their health data will not be included in the part of the study that uses past medical records.

What does the study involve?
Participants may be asked to wear a small monitoring device for up to 14 days after leaving ICU, and again for up to 14 days after leaving hospital. This device will collect health information like heart rate and activity levels. Researchers will combine this data with hospital records to better understand who is most likely to become unwell again.

What are the possible benefits and risks of participating?
There may not be a direct benefit to participants, but the information collected could help improve care for future ICU patients. The risks are low, but wearing a monitor might feel uncomfortable or inconvenient for some people.

Where is the study run from?
Oxford University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2024 to November 2027

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

Who is the main contact?
Dr Sarah Vollam, ccrg.research@ndcn.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
346848

Protocol serial number
PID18655

Study information

Scientific Title
PROgnosiS Prediction after Enhanced or CriTical care - A cohort study

Acronym
PROSPECT

Study objectives
To develop and validate a machine-learning prediction model for ICU readmission, cardiac arrest, or death following ICU discharge using routinely collected data.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 20/05/2025, South Central Hampshire A (Kadoorie Centre for Critical Care Research, Headington Oxford, OX3 9DU, United Kingdom; +44 2071048120; hampshirea.rec@hra.nhs.uk), ref: 25/SC/0136

Study design
Multi-centre observational cohort study with an embedded feasibility study and exploratory qualitative study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Patients admitted to intensive care

Interventions
This is a multi-centre observational cohort study of adult patients admitted to ICUs with an embedded feasibility study and exploratory qualitative study. The study will be split into several sub-studies and build on previous work.
This work will be undertaken in several steps, following the MRC guidelines for development and testing of complex interventions.

Step 1: We will assemble a pseudonymised dataset from a retrospective cohort of patients discharged from ICU to develop a machine learning prediction model to estimate the risk of clinical deterioration following ICU discharge — including patients' post-ICU in-hospital stay and in the early period following hospital discharge. We will validate this model using a prospective dataset.

Step 2: We will assess whether incorporating data from a digital system including wearable monitoring (already established in other in-hospital populations) improves the performance of the prediction model. This stage will include a pilot feasibility study where we will work with clinical staff and patients to understand how best to use the information from this monitoring system in clinical practice.

This study will include a prospective, patient monitoring cohort:
Patients in the ICU will be approached for consent to participate in a study involving wearable monitoring devices. Wearable devices include an adhesive chest patch measuring heart rate, respiratory rate, step count, position (e.g. lying or standing) and other data related to activity, and a wrist-worn pulse oximeter, measuring pulse and peripheral oxygen saturations. Devices transmit data to a tablet computer via blue-tooth. The study includes two phases: hospital monitoring, where patients will wear devices to monitor vital signs after ICU discharge, and home monitoring, where they will continue using the devices for 14 days post-hospital discharge.

Clear instructions will be provided to the participants for the use of the equipment at home. The research team will check data regularly, and patients will be contacted as needed to ensure appropriate device usage. At the end of the study, patients will complete questionnaires and will be invited to be interviewed about their experience. Follow-up will occur at 3 to 6 months post-discharge to collect healthcare data, with the study lasting approximately 4 to 7 months.

Intervention Type
Other

Primary outcome(s)
To develop a machine-learning prediction model for ICU readmission, cardiac arrest, or death following ICU discharge, routinely collected data will be used to assemble a bespoke retrospective database containing clinical outcomes including:
- Admission times, medical/surgical speciality, age, gender, ethnicity, mortality, ward locations /transfers
- Vital signs recording systems (e.g., blood pressure, heart rate)
- Intensive care patient records
- Laboratory information
- Medicines administered
- Blood gas analysis
- Electrocardiogram systems
- Echocardiogram systems
- Microbiology and virology
- Pathology
- General Practice (GP) summary or record systems

Key secondary outcome(s))
To test the feasibility of continuously monitoring vital signs (heart rate, oxygen saturation, temperature and blood pressure) and actigraphy in ward patients discharged from ICU, and to validate the performance of the model developed in the primary outcome:
1. Heart rate is measured using wearable continuous monitoring devices and spot-check devices at 12-hour intervals during the first 14 days post-ICU discharge or until hospital discharge and at 12-hour (continuous) or 24-hour (spot-check) intervals for 14 days post-hospital discharge
2. Oxygen saturation is measured using wearable continuous monitoring devices and spot-check devices at 12-hour intervals during the first 14 days post-ICU discharge or until hospital discharge and at 12-hour (continuous) or 24-hour (spot-check) intervals for 14 days post-hospital discharge
3. Temperature is measured using wearable continuous monitoring devices and spot-check devices at 12-hour intervals during the first 14 days post-ICU discharge or until hospital discharge and at 12-hour (continuous) or 24-hour (spot-check) intervals for 14 days post-hospital discharge
4. Blood pressure is measured using wearable continuous monitoring devices and spot-check devices at 12-hour intervals during the first 14 days post-ICU discharge or until hospital discharge and at 12-hour (continuous) or 24-hour (spot-check) intervals for 14 days post-hospital discharge
5. Physical activity is measured using actigraphy devices at 12-hour intervals during the first 14 days post-ICU discharge or until hospital discharge and at 12-hour intervals for 14 days post-hospital discharge
6. Falls are measured using actigraphy-based fall detection algorithms at 12-hour intervals during the first 14 days post-ICU discharge or until hospital discharge and at 12-hour intervals for 14 days post-hospital discharge

Completion date
30/11/2027

Eligibility

Key inclusion criteria
Retrospective dataset: Adult patients admitted to a general adult intensive care unit at one or more of the study sites between 1st December 2015 and 31st January 2025 inclusive
Prospective dataset: Adult patients admitted to a general adult intensive care unit at one or more of the study sites between 1st September 2025 to 30th November 2027 inclusive

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients that have informed their participating site that they do not wish their electronic records to be used for this study (study-specific dissent)
2. Patients who have opted out in the National Data Opt-Out

Date of first enrolment
01/11/2025

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
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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

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 pseudonymised datasets generated and/or analysed during the current study will be available upon reasonable request from the Chief Investigator, Professor Peter Watkinson (ccrg.research@ndcn.ox.ac.uk), subject to appropriate governance approvals. Data will become available following completion of primary analysis and publication and will be retained for a minimum of five years. Access will be granted only to researchers with a clear scientific rationale. Requestors must have an appropriate formal relationship with the University of Oxford (e.g. employment, honorary contract, or recognised collaborator status) and complete all necessary information governance training. Only pseudonymised data will be shared. No identifiers or re-identification keys will be made available. All data access will occur within secure analysis environments, in accordance with approved study procedures and University information governance policies. Data cannot be made publicly available due to ethical and legal restrictions, including the use of confidential patient information under Section 251 support.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes