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WARD-AMS is a study to determine whether the Portrait ambulatory monitoring system improves the time taken to detect progressive worsening of health for patients cared for on a general ward

Submission date	**Recruitment status**	[X] Prospectively registered
20/05/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/05/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/06/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Failure to detect clinical deterioration on general ward areas is a significant patient safety risk. Over recent years technology has become available that can be used in this setting and we know that this technology receives favourable feedback from patients and staff. However, there is little data on clinical outcomes and this is what we are now starting to explore.
The aim of this study is to determine whether the Portrait ambulatory monitoring system improves the time taken to detect progressive worsening of health for patients cared for on a general ward

Who can participate?
Post-surgery patients admitted on the general surgical ward.

What does the study involve?
If a participant agrees to take part in the study, they will sign an Informed Consent Form and then will be fitted with the Portrait Monitoring sensors. One sensor will be attached to their index finger to record level of oxygen and pulse rate and two chest sensors to record respiration rate. Thereafter they will be randomly allocated using Web based randomisation process to one of the two groups ‘alert versus no alert’. The monitor will continuously capture vitals for both arm participants but for alarm alert group, the device will be activated to generate alert alarms to identify any change in their oxygen level, pulse and respiration rate (i.e., they going low or high) which needs attention the monitor will send an alarm to the healthcare team enabling care and/or treatment escalation if needed. For participants I n the No alarm group the device will not be activated to generate such alert alarms. But, the medical staff will continue to monitor you throughout the duration of the trial and will be able to notice and identify change in your oxygen levels, Pulse or Respiration and will provide care and/or treatment escalation if needed. All participants, in both groups, will continue to be monitored by the nursing staff by measuring

their vital signs manually every 4-6hours. Only this information will be recorded on the electronic patient records.

What are the possible benefits and risks of participating?
The risks related to this research are likely to be minor. You may notice minor skin irritation from wearing the sensor patches (please let staff know straight away if you notice this). Some people may find it uncomfortable to have a monitor strapped to them, however, it has been designed to be small and not interfere with your daily activities or have any impact on your recovery.

Where is the study run from?
Chelsea and Westminster Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2023 to June 2026

Who is funding the study?
GE Precision Healthcare LLC (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
335808

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61589, IRAS 335808

Study information

Scientific Title
The ward alerting and ambulatory monitoring study

Acronym
WARD-AMS

Study objectives
Patient deterioration in hospital can be detected by changes in physiological parameters, but delayed detection of deterioration is a major cause of morbidity and mortality.
Vital sign changes, measured as part of routine clinical care for hospitalised patients, may be present several hours before clinical events such as cardiac arrest, death and intensive care unit admission. Unfortunately, existing systems are not reliably detecting deteriorating patients early on, and 39% of acute emergency patients admitted to critical care units are referred late.

Novel wearable sensors may identify deteriorating patients in a timelier way through continuous monitoring. These new devices can measure vital signs early and more frequently than standard current nursing monitoring. They are seen as a positive tool in detecting patient deterioration. Previous work has demonstrated that ambulatory monitoring systems using wearable sensors can be implemented on general ward areas with positive feedback from patients and staff. This study proposal seeks to extend this work to explore the implementation and clinical effectiveness of ambulatory monitoring systems, to assess cost effectiveness, as well as understand how best to integrate and promote them and test alerting protocols and systems. The aim of this study is to determine whether the Portrait ambulatory monitoring system improves the time taken to detect progressive worsening of health for patients cared for on a general ward

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 18/04/2024, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8243; bradfordleeds.rec@hra.nhs.uk), ref: 24/YH/0073

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Detection of clinical deterioration on general ward areas

Interventions
Potential participants will be identified by the direct care team as per the inclusion / exclusion criteria. If the participant agrees to be part in the study the research team will fit the wearable sensors once informed consent is obtained. Monitoring will then commence and will last until discharge from the ward (anticipated 3 days on average due to the average length of stay on the wards).
Participants will be randomised to one of two groups alerting versus no alerting. - In the no alerting group- the sensors will collect all the data but no alerts will be sent to care givers. In the alerting group - alerts will be sent to care givers. The alert parameters have been defined from the previous work.
Participants will be asked to complete a questionnaire outlining their experience pre discharge and an interview will be conducted over telephone after 2 weeks of discharge. Healthcare staff involved in caring trial participants will be asked to complete a survey regarding their experience using the device. Around 50 Healthcare staff involved in caring trial participants will also be interviewed at the end of the trial.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1.Heart rate is measured continuously from baseline to the end of the monitoring period
2.Oxygen saturations are measured using pulse oximetry continuously from baseline to the end of the monitoring period
3.Respiratory rate is measured continuously from baseline to the end of the monitoring period
4.Blood pressure is measured using a standard blood pressure cuff every 4 hours from baseline to the end of the monitoring period
5.Temperature is measured using a digital thermometer every 4 hours from baseline to the end of the monitoring period
6.Pain is measured using the visual analogue scale (VAS) every 4 hours from baseline to the end of the monitoring period

Key secondary outcome(s))
1.Patient satisfaction is measured using standardized questionnaires at discharge
2.Patient experience is measured through structured telephone interviews within 2 weeks of discharge
3.Staff feedback is measured using standardized questionnaires after final recruitment
4.Staff insights are measured through structured interviews after final recruitment

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Admitted to the general surgical ward on the West Middlesex University Hospital site
2. Aged 18 years or above
3. Capable of giving informed consent
4. Able and willing to wear the Portrait Mobile System

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Under 18 years of age
2. Incapable of giving informed consent
3. Previous history sensitivity to ECG/sensor electrodes
4. Presence of implantable cardiac pacemaker
5. Has already taken part in this study or is a current participant in another study
6. Under the influence of alcohol or drugs as assessed by the caring clinician

Date of first enrolment
22/11/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
West Middlesex University Hospital
Twickenham Road
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TW7 6AF

Sponsor information

Organisation
Chelsea and Westminster Hospital NHS Foundation Trust

ROR
https://ror.org/02gd18467

Funder(s)

Funder type
Industry

Funder Name
GE Precision Healthcare LLC

Results and Publications

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

IPD sharing plan summary
Data sharing statement to be made available at a later date