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Making surgery safer: Testing a wireless monitoring patch on general surgery wards

Submission date
03/07/2017

Recruitment status
No longer recruiting

Registration date
30/08/2017

Overall study status
Completed

Last Edited
19/09/2023

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Up to a third of patients who have major surgery will experience a serious complication, such as infection. Identifying complications early makes them easier to treat and improves the results for the patient. One of the ways patients are monitored for complications is by charting their vital signs: blood pressure, heart rate, breathing rate and temperature. The nurse looking after the patient will usually check these signs every few hours in the days after surgery. The vital signs are used to form a score, the National Early Warning Score (NEWS), which can alert if the patient becomes unwell. One of the problems with NEWS is that patients can deteriorate in the interval between monitoring, which can delay vital treatment. One solution to this problem is continuous monitoring. We are testing a wireless monitoring patch that continuously monitors heart rate, breathing rate and temperature. This information is sent wirelessly every two minutes to a mobile phone carried by the nurse, which alerts if the vital signs become abnormal. This could help detect unwell patients earlier than traditional monitoring, but not enough is known about this technology to say for sure. This is why it has to be tested against the current national standard of care: NEWS monitoring. In order to test this theory, a study will be done comparing the patch system with NEWS monitoring. The main aim is to provide information about whether the research works, and if the patch improves results for patients having major surgery.

Who can participate?
Adults aged 18 and older who are having planned major surgery and returning to one of these wards afterwards.

What does the study involve?
Participants are randomly allocated to receive one of two types of monitoring during their hospital stay. Those in the first group receive standard NEWS monitoring alone. Those in the second group receive the NEWS monitoring and the continuous monitoring patch. All other care will be the same as those who are not in the study. Researchers will collect data about how the trial is running, and any complications the patients experience.

What are the possible benefits and risks of participating?
For patients in the NEWS monitoring group, care will not vary from that of someone who is not

taking part in the research, although information about their hospital stay will be collected. Patients who receive the monitoring patch will have the patch applied in the Recovery Room after their operation. This process is painless, but takes 5-10 minutes and may involve some skin preparation of the area on the chest where the patch is applied. This sometimes includes shaving small areas for the patch to stick to. The patch's battery lasts for five days. These patients will be expected to wear a patch for the whole of their hospital stay. This may mean getting the patch changed a number of times, if they are in hospital for a few weeks. Once the patch is applied, the patients are free to move about as normal. The patch is not connected to any machines and does not limit movement. At the end of the patient's hospital stay, the patch will be removed and they will be asked to share their views about the monitoring they have received.

Where is the study run from?
St. James's University Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to September 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Candice Downey
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
35024

Study information

Scientific Title
Trial of Remote Continuous vs Intermittent Vital Signs Monitoring after Major Surgery

Acronym
TRaCINg Study

Study objectives
The aim of this study is to compare a continuous monitoring system with NEWS monitoring to provide information about how best to undertake a larger study to fully test the new monitoring system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & the Humber – Leeds West Research Ethics Committee, 28/07/2017, 17/YH/0180

Study design
Randomised; Interventional; Design type: Diagnosis, Prevention, Device, Complex Intervention, Management of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Surgery, Primary sub-specialty: General Surgery; UKCRC code/ Disease: Generic Health Relevance/ No specific disease

Interventions
Participants are individually randomised (stratified for gender and comorbidity) to receive either standard NEWS monitoring (control arm) or SensiumVitals monitoring and NEWS monitoring (intervention arm). The patients will remain in their allocated monitoring arm for the duration of their hospital stay. After discharge from hospital they will be followed up for 30 days to see if they are readmitted.

Intervention Type
Other

Primary outcome(s)
1. Recruitment is determined by recording the number of patients eligible, approached, consenting and randomised. Recruitment rate will be calculated as the number of patients randomised out of the number of patients eligible. The proportion of ineligible patients will be calculated as the number of patients ineligible out of the number of patients approached.
2. Adherence to protocol, and reasons for non-adherence as defined by the number of patients who do not receive the correct type of monitoring as per randomisation (and reasons for this) and the number of patients who do not wear the patch for their entire hospital stay or at least five days during their admission (and reasons for this including failure to repatch after return

from critical care).
3. The amount of missing data for a data item will be calculated as the proportion of missing data for that item out of the number of patients randomised. Loss-to-follow-up will take into account withdrawal and death. The proportion of patients who are classed as 'drop-out' by design (i.e. never being admitted to a participating ward) will be calculated using the number of patients randomised as the denominator.
4. Optimal outcome measures to test effectiveness. This will be determined by observing effectiveness endpoints (see below) such as time to administration of antibiotics in cases of sepsis, critical care admission rate, length of hospital stay and assessing their potential as primary outcome measures for the definitive study. Assessment of the optimal outcome measures will take into consideration the amount of missing data and summary statistics for each potential outcome.
5. Estimation of sample size for definitive RCT will be calculated using relevant effect size(s) as seen in the effectiveness endpoint(s).

Key secondary outcome(s))

1. Time to antibiotics in cases of sepsis will be calculated as the time in minutes between the first evidence of sepsis on either or both monitoring tools and the first administration of antibiotics to the patient, and determined using the electronic patient record. Clinical suspicion of sepsis is defined by the presence of a likely source of infection and 2 or more criteria from a collection of clinical signs and laboratory investigations as follows:
1.1. Temperature >38.3°C or <36.0°C
1.2. Tachycardia >90 beats per minute
1.3. Tachypnoea >20 breaths per minute
1.4. pCO2 <4.3 kPa
1.5. Hyperglycaemia (blood glucose >6.6 mmol/) in the absence of diabetes mellitus
1.6. Acutely altered mental status
1.7. WBC count >12×10^9/L or <4×10^9/L
2. Number of HDU/ICU admissions defined as any admission to Level II/III care after stepdown to the general wards (i.e. non-perioperative admission from a participating ward) following surgery, and determined using the electronic patient record
3. Length of stay in HDU/ICU in days per admission, calculated as the difference in days between date of admission to either HDU/ICU and date of discharge from HDU/ICU, and determined using the electronic patient record. HDU and ICU lengths of stay will be amalgamated into a total HDU /ICU length of stay (excluding any peri-operative crtitical care admission)
4. Total length of stay in hospital in days per admission, including perioperative and postoperative Level II/III care, calculated as the difference in days between the date of admission and date of discharge, and determined using the electronic patient record
5. Number of postoperative complications, defined as any complication occurring after the patient has left the theatre complex and returned to wards J44 or J45 (i.e. not including perioperative HDU/ICU post-operative complications), and determined using the electronic patient record
6. Number of re-interventions, defined as the number of medical, radiological and surgical interventions required to treat postoperative complications, and determined using the electronic patient record. The proportion of patients receiving at least one re-intervention will be presented using as the denominator the number of patients receiving on-trial monitoring (i.e. admitted to a participating ward at some point during their stay)
7. Patient acceptability, as determined by the patient questionnaire and semi-structured interviews, and focus groups throughout the study
8. Nursing acceptability, as determined by the Modified System Usability Score and semi-structured interviews throughout the study

9. 30-day readmission rate, defined as the number of patients who are admitted to hospital for any reason within 30 days of discharge from their index admission, and determined using the electronic patient record

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Patients who are undergoing elective surgery
2. Patients who have the capacity to provide informed, written consent on admission
3. All ages >18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
136

Key exclusion criteria
1. Patients who have undergone emergency surgery
2. Those who do not consent
3. Allergy to adhesives on electrodes
4. Cardiac pacemaker in situ

Date of first enrolment
04/09/2017

Date of final enrolment
10/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St. James's University Hospital
Beckett Street
Leeds
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LS9 7TF

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from c.l.downey@leeds.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/11/2020	04/03/2021	Yes	No
Results article	Reliability data from the remote monitoring arm	15/08/2019	19/09/2023	Yes	No
Protocol article	protocol	11/06/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3	28/06/2017	26/10/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes