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Remote vital signs monitoring in surgical patients

Submission date
15/12/2016

Recruitment status
No longer recruiting

Registration date
19/12/2016

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Patients having surgery are at high risk of complications, some of which can be life threatening. Identifying complications early makes them easier to treat and improves the outcome 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 four hours in the days after surgery. They are used to form 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. This study is looking at a monitoring system that measures heart rate, breathing rate and temperature continuously. It is a wearable, wireless patch that is applied to the patient's chest and alerts the nurse if the patient's vital signs become abnormal. This could help detect unwell patients earlier than NEWS monitoring. The aim of this study is to find out whether this monitoring system is a feasible and effective way of monitoring surgical patients and if using it can improve patient outcomes.

Who can participate?
Adult patients admitted to participating surgical wards.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the continuous monitoring alongside standard NEWS monitoring. Those in the second group receive standard NEWS monitoring alone. Patients are followed up during their hospital stay to see if any complications occur and how quickly they are detected until they are discharged from hospital.

What are the possible benefits and risks of participating?
The potential benefit of receiving a monitoring patch is closer monitoring during the patient's hospital stay. Any risks are likely to be small, but will be monitored throughout the study.

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 2015 to July 2017

Who is funding the study?
Health Foundation (UK)

Who is the main contact?
Miss Candice Downey
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Contact information

Type(s)
Public

Contact name
Ms Candice Downey

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32955

Study information

Scientific Title
An evaluation of remote, near-continuous vital signs monitoring in patients admitted to surgical wards

Study objectives

The aim of this study is to evaluate whether continuous remote vital signs monitoring is a feasible and effective way of monitoring surgical patients and if its use improves patient outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 30/11/2016, ref: 16/YH /0426

Study design
Randomised; Interventional; Design type: Diagnosis, Prevention, Device, Management of Care, Surgery, Active Monitoring

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Surgery, Primary sub-specialty: Other; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
Patients will be pseudo-randomised to either study arm according to which bay they are admitted into on the participating wards.

Patch bays: Patients will receive SensiumVitals monitoring and usual National Early Warning Score (NEWS) monitoring.
Non-patch bays: Patients will receive NEWS monitoring alone.

Patients will be approached when they are admitted to the participating wards. They will remain in the study arm to which they are allocated for the duration of their stay on the participating wards. On discharge from hospital, their participation in the trial will be over.

Intervention Type
Other

Primary outcome measure

Time to antibiotics in patients who are diagnosed as suffering from sepsis is measured by review of the observations chart, the SensiumVitals data, the electronic medications record and the medical notes of the patient during their hospital admission.

Secondary outcome measures
1. In-hospital mortality is measured by review of the patient's medical notes at the point of discharge
2. Length of hospital stay is measured by review of the patient's medical notes at the point of discharge
3. Number of admissions to Level II/III care is measured by review of the patient's medical notes at the point of discharge
4. Length of stay at Level II/III is measured by review of the patient's medical notes at the point of discharge
5. Patient satisfaction is assessed by questionnaire and/or structured interview on discharge
6. Staff satisfaction is assessed by questionnaire and/or structured interview at a time convenient for the participant and at least 2 months after the commencement of recruitment

Overall study start date
05/09/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. All patients admitted to one of the participating wards
2. Aged 18 years or over
3. Able to provide informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria
1. Those who do not consent
2. Allergy to adhesives on electrodes
3. Cardiac pacemaker in situ

Date of first enrolment
09/12/2016

Date of final enrolment
26/05/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
St James's University Hospital
United Kingdom
-

Sponsor information

Organisation
University of Leeds

Sponsor details
-
Leeds
England
United Kingdom
LS2 9JT
+44 (0)113 34 37587
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Publication and dissemination plan

This research has already been presented at the Extreme Medicine Conference (London, October 2015) and as a piece on the BBC's One Show.
Other dissemination plans, at the end of the project, include:
1. Presentation to the Trust Clinical Governance Board.
2. Presentations at local and national clinical meetings to disseminate the findings.
3. Publication of the study in a peer-reviewed journal e.g. British Journal of Surgery, likely December 2017
4. Dissemination through the NIHR HTC in Colorectal Therapies network with reach to healthcare workers throughout the NHS
5. Engagement with NIHR Local Clinical Research Networks
6. Engagement with professional bodies (Association of Coloproctology of GB&I, Association of Surgeons of GB&I, British Association of Nursing etc.) to inform relevant healthcare workers
7. Use of existing patient and public forums (e.g. Bowel Cancer UK, Crohn's and Colitis Association) to inform the wider public
8. Engagement of media outlets, including the Trust Press Office, and local and national news agencies

Intention to publish date

31/07/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Miss Candice Downey (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?
Participant information sheet	version V3	26/10/2016	19/12/2016	No	Yes
Results article	results	11/12/2018		Yes	No
Protocol file	version 1	17/05/2016	17/08/2022	No	No
HRA research summary			28/06/2023	No	No