

# Remote vital signs monitoring in surgical patients

<b>Submission date</b> 15/12/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/08/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> 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  
c.l.downey@leeds.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Ms Candice Downey

### ORCID ID

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### Contact details

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## Additional identifiers

### Protocol serial number

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

## **Primary study design**

Interventional

## **Study design**

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

## **Study type(s)**

Treatment

## **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(s)**

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.

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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

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# Sponsor information

## Organisation

University of Leeds

## ROR

<https://ror.org/024mrx33>

# Funder(s)

## Funder type

Government

## Funder Name

Health Foundation

# Results and Publications

## 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](mailto: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?
<a href="#">Results article</a>	results	11/12/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version V3	26/10/2016	19/12/2016	No	Yes
<a href="#">Protocol file</a>	version 1	17/05/2016	17/08/2022	No	No