ISRCTN58660550 https://doi.org/10.1186/ISRCTN58660550

Does continuous monitoring of vital signs with an alerting system reduce length of hospital stay in post-operative upper gastro-intestinal surgery patients?

Submission date
08/06/2017

Recruitment status
No longer recruiting

Registration date
11/08/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
After surgery, all patients have their vital signs measured. These include pulse, blood pressure, breathing rate, temperature and the body's oxygen levels. Nurses can do this by hand or automatically using a machine called a monitor. It isn't clear whether it is better to take these measurements by hand at certain times or by machine all the time. In addition, it is not known whether current monitors could provide better information for the doctors and nurses caring for patients. This study is looking at whether a new attachment called the 'Software Monitor' makes monitors more reliable and useful to medical staff. The Software Monitor uses new computer technology developed in Oxford. If the Software Monitor proves to be successful it could improve both nurses' and doctors' abilities to watch over patients. It could also alert them earlier to a patient who may be in need of more treatment, a different type of care, or more or less monitoring. This may help patients to go home from hospital earlier. The aim of this study is to find out whether continuous monitoring with the Software Monitor is more effective than current paper-based systems.

Who can participate?
All patients admitted to the Oxford Radcliffe Hospitals NHS Trust for upper gastro-intestinal (digestive system) surgery

What does the study involve?
Patients who have had surgery on the digestive system are admitted to the surgical ward. On the ward they are connected to standard hospital monitors that measure heart rate, blood pressure, temperature, and the amount of oxygen in the blood. For those that agree to take part in this study, there is an extra 'Software Monitor' attached to the hospital monitor. The 'Software Monitor' continuously records what the hospital monitor is displaying to give the nurses and doctors an extra measurement. Participants wear the monitor for the duration of their hospital stay. When the surgical doctors are happy that participants are well enough to go home, they are disconnected from the monitor and their time in the study ends.

What are the possible benefits and risks of participating?
There may be a clinical benefit to participants from taking part in this study. Participants in this study will be monitored on the surgical wards until their doctors say they are well enough to be discharged. Although patients may be connected to a monitor for longer than normal, the equipment is portable so that the participant can move about. In future, it is hoped that this study will contribute to improved standards of care received by surgical patients, based on the information we record. There are no notable risks involved with participating.

Where is the study run from?
John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2008 to December 2014

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

Who is the main contact?
Dr Peter Watkinson

Contact information

Type(s)
Scientific

Contact name
Dr Peter Watkinson

Contact details
Kadoorie Centre
Level 3
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6361

Study information

Scientific Title
Does continuous monitoring of vital signs with an alerting system reduce length of hospital stay in post-operative upper gastro-intestinal surgery patients? A non-randomised study

Acronym
CALMS 2 (Computer ALerting Monitoring System 2)

Study objectives
Does continuous monitoring of 'vital signs' with computer-modelled alerting to detect patient deteriorations reduce patients' length of stay in hospital by alerting staff to clinical deteriorations more effectively than current paper-based systems?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Phase 1 and 2:
Ethics Committee: Mid and South Bucks , 09/12/2008, ref: 08/H0604/79

Phase 3 and 4*:
Ethics Committee: Leeds (West), 20/05/2011, ref: 11/YH/0056

*Phase 3 and 4 had a seperate ethics committee review due to the intended addition of non-CE marked respiration software. This was subsequently deemed not to be ready for patient application therefore was not included. There is no change in study design or outcomes between the two submissions.

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Link to protocol and participant information sheet: https://ora.ox.ac.uk/objects/uuid:0307ad80-e96b-47f6-bb2b-c8f4ad1fd7c2

Health condition(s) or problem(s) studied
High-risk upper gastro-intestinal surgical patients

Interventions

A clinical trial of a 'Computer-Alerting Monitoring System' compared with the standard 'Track-and-Trigger' system in elective upper GI surgical patients. The study will be divided into four phases:

Phase One (1 month)
Training period for research nurses in the processes of the trial and on the technology utilised.

Phase Two (1 year, 200 patients)
Phase two has two purposes, to generate the control group ("pre-intervention") data and to calibrate the data fusion algorithm. The study design allows both to proceed simultaneously. Consenting patients will be monitored using conventional 'Track-and-Trigger' scoring until deemed fit for discharge by the surgical team. A 'Track-and-Trigger' alarm will activate a clinical response algorithm, including rapid review by Intensive Care services. Simultaneously, all consenting patients will be monitored from first return to the ward using the normal ward bedside monitor with study system attached. Patients will be transferred to a telemetry monitoring system which allows continuous monitoring of heart rate and pulse oximetry combined with intermittent blood pressure, respiratory rate and temperature recordings until the patient is deemed fit for discharge by the surgical team. The results of the 'Computer-Modelled Alerting System' (i.e. the derived vital signs score) will not be available to the attending staff. Patients will wear the monitoring until deemed by the surgeons as fit for discharge, or until they wish to discontinue monitoring. Data will be collected throughout hospital stay. Patients will be followed up 30 days after hospital discharge.

Phase Three (1 month)
The 'Computer-Modelled Alerting System' will be employed at each monitored bed space. Staff will be educated in its use but will not be asked specifically to use it in clinical decision-making.

Phase Four (1 year, 200 patients)
The 'Computer-Modelled Alerting System' will be in place, utilising the monitoring data from each patient. All consenting patients will be monitored from first return to the ward. Initially this will be using a bedside monitor with the study system attached. When fit enough to get out of bed, patients will be transferred to a telemetry system (which is designed to be portable) which will allow continuous monitoring of heart rate and pulse oximetry combined with intermittent blood pressure, respiratory rate and temperature recordings until the patient is deemed fit for discharge by the surgical team (as in phase two). The main difference between these two monitors is the freedom of the patient to move around while attached. The 'Computer-Modelled Alerting System' will be used overtly in clinical decision-making, with staff using a clinical algorithm response, which will include rapid review by Intensive Care services. Throughout phase four the standard 'Track-and-Trigger' system will remain in use, as per normal care on the ward. Data will be collected as in phase two. Patients will wear the monitoring until deemed by the surgeons as fit for discharge, or until they wish to discontinue monitoring. Data will be collected throughout hospital stay. Patients will be followed up 30 days after hospital discharge.

Intervention Type
Device

Primary outcome measure
Length of stay is measured from first return to the ward following initial surgery, to the time at which the surgeon deems the patient fit for hospital discharge. This will be measured once the patient has been discharged from hospital

Secondary outcome measures

1. Mortality determined from hospital records at the point of hospital discharge or death
2. Unplanned ICU admission determined from the ICU electronic record at the point of hospital discharge or death. It is defined as any ICU admission which occurs after initial surgery and only after the patient is admitted to the surgical ward
3. Clinical deteriorations defined with a pick list using data collected from patient records by research nurses throughout hospital stay. Analysis of this will be completed after the end of the study
4. Sensitivity, specificity, positive and negative prediction values of computer-modelled alerting analysed using data collected throughout hospital stay. This analysis will be completed after the end of the study

Overall study start date
01/05/2008

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. All patients admitted to the Oxford Radcliffe Hospitals NHS Trust for Upper Gastro-Intestinal Surgery. This will include patients undergoing the following procedures: oesophagectomy, oesophagogastrectomy, gastrectomy, whipples, liver resection, pancreatectomy, gastric bypass, billiary reconstruction and splenectomy.
2. Willing and able to give consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Total final enrolment
407

Key exclusion criteria
1. Patients refusing consent
2. Children (less than 16 years old)
3. Prisoners
4. Pregnant women
5. Patients whose anatomy precludes the use of the required monitoring
6. Patients who are judged to lack capacity at the time of consent
7. Patients who cannot understand written English and for whom no translator can be found

Date of first enrolment
01/05/2009

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Kadoorie Centre
Oxford University Hospitals NHS Foundation Trust
Headley Way
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Sponsor information

Organisation
Oxford University Hospitals NHS Foundation Trust

Sponsor details
Research & Development Office
Manor House
John Radcliffe Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Peter Watkinson.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2018	26/11/2020	Yes	No