

A study comparing the effects of using an automated electronic system and a paper-based system of recording patients observations on the length of stay in a hospital for trauma patients

Submission date 10/05/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/11/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In current practice, each time a set of observations (blood pressure, heart rate etc) are performed they are recorded on a paper chart. Each result is given a score. The scores for each observation are manually summed, and the total score is recorded on the paper chart. If the total score is too high, the nurse at the bedside will respond by asking for help from a doctor or senior nurse. This method for helping doctors and nurses to recognise when patients are becoming unwell is called an Early Warning System. In 2007 the National Institute of Clinical Excellence advised that wards use an Early Warning System and recommended that the use of electronic systems to facilitate the process should be investigated. The study will test whether recording medical observations electronically can help doctors and nurses to improve outcomes for patients.

Who can participate?

Any patient over 16 years of age admitted to the John Radcliffe Hospital (wards 2A and 3A) in Oxford over an eight month period.

What does the study involve?

Whilst a patient is in hospital their medical observations will be recorded either using the paper-based system or using the electronic system. This will depend on which part of the ward a patient is initially admitted to. The nursing staff are guided to perform exactly the same observations on the patients regardless of whether the results of those observations are being recorded on paper or electronically.

To investigate whether there are any differences between the paper-based and electronic methods of recording the observations we ask trained nursing staff to look at the patients' medical notes.

What are the possible benefits and risks of participating?

The implementation of an electronic based track and trigger system may improve relevant patient outcomes in comparison to an optimised paper based version. There are no known risks for this study. Only data collected from the patients stay will be used.

Where is the study run from?

The study is being carried out on the Trauma unit at the John Radcliffe Hospital (wards 2A and 3A)

When is study starting and how long is it expected to run for?

August 2011 to July 2012

Who is funding the study?

Biomedical Research Council (UK)

Who is the main contact?

The main contact for any questions regarding this study is the OTEST study research team, who can be contacted on 01865 572282.

Dr Peter Watkinson, Principal Investigator for the study and Intensive Care Consultant, can be contacted via The John Radcliffe Hospital, Headley Way, Oxford OX3 9DU. Tel: 01865 741166.

Contact information

Type(s)

Scientific

Contact name

Dr Peter Watkinson

ORCID ID

<http://orcid.org/0000-0003-1023-3927>

Contact details

Oxford University Hospitals NHS Trust

John Radcliffe Hospital

Kadoorie Research Centre

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Oxford Track-&-Trigger Electronic System for Trauma (OTEST) - a randomised stepped wedge trial comparing the effects of an integrated electronic 'Track-and-Trigger' system and a paper-based 'Track-and-Trigger' system on the length of trauma patients stay from admission date to 'fit for discharge'

Acronym

OTEST

Study objectives

Will the implementation of an electronic based track and trigger system improve relevant patient outcomes in comparison to an optimised paper based version?

The null hypothesis in this trial is that the electronic 'Track-and-Trigger' system will not affect the time between admission to the ward and 'fit-to-discharge' in comparison to a paper-based system; the alternative hypothesis that the electronic 'Track-and-Trigger' system will affect the time between admission to the ward and 'fit-to-discharge' in comparison to a paper-based system.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 2 Research Ethics Committee, 17/02/2011, ref: 11/HO308/11

Study design

Single-centre randomised stepped wedge interventional study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Patients admitted to a trauma ward

Interventions

Control 'paper system' arm:

A paper evidence-based 'track-and-trigger' system on which physiological observations of blood pressure, pulse, oxygen saturation, temperature and conscious level are recorded is used. A score is manually assigned to each observed physiological value dependent on that value's position within the range of values seen in hospitalised patients. The scores for each physiological value are manually summed to provide a single (summary) measure of the patient's physiological status. The frequency of subsequent observations and the clinical response to a patient's physiological status are then set by following an algorithm based on the summary measure. The control arm is essential to allow comparison with the current standard system, a comparison recommended by the National Institute for Clinical Excellence. Observation time is no longer than the patient's hospital stay. No follow-up other than survival at 30 days after admission.

Intervention 'electronic system' arm:

Physiological observations will be entered onto a tablet personal computer or personal digital assistant both integrated with a central display station. Scores will be automatically assigned and summed. The time of the next observation set and the appropriate clinical response will be automatically displayed according to the escalation algorithm. Visual warnings will be displayed if an observation set or clinical response is delayed. This study will use the VitalPAC v 1.2 system (The Learning Clinic, UK) to provide this functionality. The product and its software will be fully localised to both trust standards and those specific to the trauma unit (and has already been deployed in several NHS Trusts). Observation time is no longer than the patient's hospital stay. No follow-up other than survival at 30 days after admission.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Time from ward admission to 'fit to discharge'. 'Fit to discharge' is defined as either discharged from the ward to home or alternative care or accepted by social services as a 'delayed discharge'. This primary outcome measure has been chosen instead of using length of stay as a significant number of patients have an extended length of stay whilst waiting for suitable support mechanisms to be put in place outside hospital.

Secondary outcome measures

Patient outcome measures:

1. Hospital length of stay
2. In hospital mortality
3. 30 day mortality following ward admission
4. Unplanned admissions to intensive care
5. Number of cardiac arrest calls

Compliance measures:

1. Appropriate escalation in observation frequency
2. Appropriate escalation in clinical intervention

Overall study start date

31/08/2011

Completion date

01/07/2012

Eligibility

Key inclusion criteria

All patients over 16 years of age admitted to two trauma wards over an eight month period

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

2000

Key exclusion criteria

1. Patients whose treatment plan is palliative at admission to the trauma ward
2. Patients with a learning disability
3. Patients unable to speak English and without a suitable translator
4. Patients in the custody of HM Prison Service

Date of first enrolment

31/08/2011

Date of final enrolment

01/07/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Oxford University Hospitals NHS Trust

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

Oxford University Hospitals NHS Trust (UK)

Sponsor details

John Radcliffe Hospital
Headley Way
Headington
Oxford
England
United Kingdom
OX3 9DU

Sponsor type

Hospital/treatment centre

Website

<http://ouh.nhs.uk>

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Research council

Funder Name

Biomedical Research Council (UK)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

08/09/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/10/2018		Yes	No