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RESPOND study (Rescue for Emergency Surgery Patients Observed to uNdergo acute Deterioration)

Submission date
26/04/2023

Recruitment status
Recruiting

Registration date
24/08/2023

Overall study status
Ongoing

Last Edited
22/08/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is part of a 4-Work Package (WP) programme of research to improve how the response when a patient deteriorates after emergency surgery on the abdomen. WP1 and 2 studied existing systems for responding to deteriorating patients and developed ideas for improvement by working with frontline doctors and nurses. In WP3 these ideas were developed as clinical interventions and tested in the Emergency General Surgery units of three hospitals, using a Quality Improvement system for rapidly modifying the interventions to make them as effective as possible. In this trial, part of WP4, the programme will test the final versions of all of the interventions in a randomised trial in Emergency General Surgery units at 24 hospitals.

Who can participate?
Adult patients who have acute abdominal pain having undergone a surgical operation or other invasive therapeutic intervention since admission

What does the study involve?
The interventions include four parts or Strands: Patient Involvement Strand (Strand 1), Team Strengthening Strand (Strand 2), Systems Redesign Strand (Strand 3), and Enhancing Shared Ownership Strand (Strand 4). The study team will analyse whether the interventions decrease the number of patients who die after developing a complication and whether they reduce deaths from any cause. Those are the primary aims, but the study will also look for other important effects. The team will study whether patients in the intervention group needed less time in intensive care or fewer secondary operations. The study will measure how quickly Quality of Life improves after getting home from the hospital. The study will also estimate how much it costs to treat each patient before and after the introduction of the interventions, and how much the interventions cost to deliver. Finally, as in the pilot study (WP3), the team will interview patients, carers and staff members as the study proceeds, to understand their feelings about the interventions, and to understand why things work or don't work in different hospitals.

In Emergency General Surgery, which deals mainly with patients with severe abdominal pain, the death rate after exploratory abdominal surgery to find out what's wrong (called a laparotomy) is

five times higher than for similar routine surgery. Death rates after routine major surgery are lower in bigger hospitals than in smaller ones. it is known that this is not because larger units have fewer complications after surgery, but because they respond to them more effectively. An effective response to complications after surgery needs both early detection of problems and an efficient rescue system that can allow clinicians to respond as fast and adequately as possible to deteriorating patients. Unfortunately, monitoring patients' blood pressure, temperature, heart and breathing rates more reliably (aimed at early detection of problems) has not reduced death rates consistently, suggesting that it is more important to improve rescue systems.

Working with frontline doctors and nurses, and using Human Factors science (which analyses how complex work systems succeed or fail), the programme developed ideas for rescue system improvement, which were then used to design changes to ways of working. The study team will analyse whether the interventions decrease the number of patients who died after developing a complication and whether they reduce deaths from any cause. These are the primary aims, but other important effects will also be investigated. The team will study whether patients in the intervention group needed less time in intensive care or fewer secondary operations. The team will measure how quickly the Quality of Life improves after getting home from the hospital, comparing the intervention period with the normal treatment period. The team will estimate how much it costs to treat each patient in the two periods, and how much the interventions cost to deliver. To study all these ways of measuring the effect of the intervention, patients who became unwell after complications will be recruited and asked to consent for the team to look at their medical notes. They will also be asked to complete two short questionnaires, one about Quality of Life after they leave the hospital and the other about their use of the health service during the recovery period. The Quality of Life questionnaire will be completed before they leave the hospital, and then both questionnaires will be completed 3, 6 and 12 months after they had their surgery.

What are the possible benefits and risks of participating?
The interventions are in the patient care pathway only, and as such there are no specific benefits or risks of participating in the study.

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

When is the study starting and how long is it expected to run for?
May 2020 to October 2026

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

Who is the main contact?
respond@nds.ox.ac.uk

Study website
https://www.nds.ox.ac.uk/research/the-respond-programme

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318646

ClinicalTrials.gov number
NCT04919720

Secondary identifying numbers
CPMS 54654, IRAS 318646

Study information

Scientific Title
RESPOND study (Rescue for Emergency Surgery Patients Observed to uNdergo acute Deterioration). Work Package 4: A cluster-randomised stepped-wedge trial of a complex Human Factors intervention

Acronym
RESPOND

Study objectives
Does a complex intervention based on Human Factors science improve the ability of clinical teams to respond to patients that develop serious complications after emergency abdominal surgery and thereby decrease the risk of death for these patients?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/01/2023, South Central - Oxford C Research Ethics Committee (Health Research Authority, Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 1048144, (0)207 1048241, (0)207 1048289; oxfordc.rec@hra.nhs.uk), ref: 22/SC/0382

Study design

A multicenter cluster-randomized stepped-wedge study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
How clinical teams respond when a patient deteriorates after emergency surgery on the abdomen

Interventions
The intervention to be tested as part of this RESPOND WP4 trial includes four parts or Strands: First, a way for patients, carers or anyone visiting the ward to call an alert themselves if one of the patients in the ward becomes acutely unwell will be introduced. This is the Patient Involvement Strand. Second, clinical staff will be given training to strengthen teamwork, based on learning from elite sports and military coaches. This is the Team Strengthening Strand. Third, parts of the pathway used by clinicians to help patients who are acutely unwell will be strengthened and clarified, making it clearer what to do and when to do it and aiming to minimise errors and delays. This is the Systems Strengthening Strand. Finally, cooperation will be improved between the different departments involved in the care of emergency patients by using joint simulation exercises, and positive feedback and recognition to improve understanding. A standardised way will also be introduced for describing the condition of ill patients to other staff, to minimise misunderstandings and delays. This is the Enhancing Shared Ownership Strand.

Participating hospitals will be randomised into six groups of 4 sites to begin the interventional phase of the study at three-month intervals, beginning after an initial baseline data collection period (observational phase of the study) of 3 months for all sites. Randomisation will be by computer-generated random numbers.

To facilitate the INDUCTION and IMPLEMENTATION of the intervention, we will recruit up to 6 frontline clinical staff at each site who will act as Champions. These will be respected members of the clinical team in a range of nursing and medical roles who will help us to achieve full implementation of and engagement with the study interventions, especially during the three-month initial induction period. They will be paid for their time, either by paying for additional hours worked to their regular working hours, or by paying for back-fill costs (up to 4 hours per week, for up to 12 weeks). Whilst working in this role they will act as members of the research team rather than as staff participants.

The interventions will be delivered face-to-face, in a group. The location is the Emergency Surgery Unit.

Intervention Type
Other

Primary outcome measure
Failure to Rescue (% postoperative mortality amongst patients experiencing complications from an initial operation) measured using the percentage postoperative mortality (defined as any death within 90 days of the index operation) calculated for the population of patients who experienced a post-procedure complication at 90 days after the end of pre-intervention, observational phase of study AND 90 days after the end of the active, interventional phase of the study

Secondary outcome measures
1. Postoperative mortality measured using any death within 90 days of the index operation as for Primary outcome
2. Length of hospital stay measured using Duration of hospital stay (days) during index admission as for Primary outcome
3. Length of ITU stay measured using Average ITU stay (days) amongst patients deteriorating before versus after intervention as for Primary outcome
4.Percentage of operated patients experiencing a postoperative deterioration(complication) measured using Total number of patients listed as Primary outcome
suffering a post-intervention deterioration as a percentage of all patients undergoing any OPCS coded procedure whilst inpatients in the SEU as for Primary outcome
5. Number of additional procedures required measured using the Total number of OPCS coded procedures for each deteriorating patient during inpatient stay as for Primary outcome
6. Effectiveness of Rescue Process measured using Time from first alert to definitive treatment (from EPR notes) & Expert evaluation of response quality for each deterioration as soon as possible after the clinical event
7. Quality of Life measured using EQ-5D-5L Quality of Life questionnaire and scale at baseline (at time of consent or soon after) and subsequently at 3, 6 and 12 months after index operation
8. Use of NHS hospital-based services, treatment costs (i.e. costs associated with the introduction of new intervention in those randomised to the intervention group), community-based health and social care services, out-of-pocket medical costs, and additional care costs to patients and their families over the 12 months after index operation measured using Bespoke Health Economics Resource Use questionnaire at 3, 6 and 12 months after index operation

Overall study start date
01/05/2020

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. The patient is over 18 years old
2. The patient was admitted with acute abdominal pain
3. The patient has undergone a surgical operation or other invasive therapeutic intervention

since admission
4. The patient has undergone an acute clinical deterioration following the initial operation or intervention.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4992

Key exclusion criteria
1. Have been declared “not for resuscitation”, or have a ceiling of care that has been set which excludes further interventional procedures or ITU admission. For this exclusion to apply, the decision on limiting care must have been endorsed by a senior doctor, and recorded in the clinical record BEFORE any postoperative deterioration takes place.
2. Cannot communicate in English, and no translation facilities can be found

Date of first enrolment
01/08/2023

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Aldermaston Road
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Sponsor information

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Sponsor type
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ROR
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Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
31/03/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be stored in a non-publicly available repository, REDCap.

IPD sharing plan summary
Stored in non-publicly available repository