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A medical trial looking at ways to improve the quality and delivery of care for patients having emergency abdominal surgery

Submission date
27/02/2014

Recruitment status
No longer recruiting

Registration date
07/03/2014

Overall study status
Completed

Last Edited
03/05/2023

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
More than one million patients undergo surgery each year in the NHS, following which 30,000 patients die without leaving hospital. However, most deaths occur amongst patients who we know are exposed to much greater risks. These patients require longer hospital care and suffer a substantial reduction in functional independence and long-term survival. Advancing age, abdominal surgery and the need for emergency surgery are amongst the strongest factors that can cause problems after an operation. Around 35,000 patients come to NHS hospitals each year with precisely this pattern of risk and undergo a procedure called emergency laparotomy (major surgery to treat a life-threatening problem within the abdomen). Almost 9,000 emergency laparotomy patients will die within three months of surgery. Doctors find that these patients are particularly difficult to treat successfully. However, recent evidence shows that quite basic standards of patient care vary widely between hospitals. In particular, there are large differences in how often a senior surgeon is involved in planning and performing the surgery and the use of planned admission to intensive care after surgery has been completed. Doctors have developed guidelines which set out the important standards of care for emergency laparotomy patients which we believe will work. Unfortunately, previous attempts to implement guidelines to improve patient care on a national basis have proved challenging. By studying the effects of introducing an integrated care pathway on survival for emergency laparotomy patients we would provide robust evidence for the benefits of quality improvement projects.

Who can participate?
We expect to make use of data describing 27,540 patients undergoing emergency laparotomy over an 85-week period.

What does the study involve?
Ninety hospitals will be allocated in random order to a quality improvement intervention which will help local staff to deliver the highest possible standard of care for emergency laparotomy patients. This will avoid the need for individual patients to make a decision to take part. Instead, we will use existing systems to provide anonymous data on individual patients. The study is exploring whether fewer patients die within 90 days of surgery in hospitals where the quality

improvement project is in place. We will also find out about any effects on later deaths within 180 days following surgery, the number of days patients spend in hospital and the number of patients re-admitted to hospital. We will have in-depth observations and interviews with staff to find out how we can further improve uptake of the pathway. We will also look at the cost effectiveness of this project and evaluate the long-term effects of our intervention in the participating hospitals.

What are the possible benefits and risks of participating?
There is a high likelihood of benefit to patients in participating hospitals. Learning from this study may help other people undergoing such surgery in the future.

Where is the study run from?
The study is led by Queen Mary University London (QMUL), in collaboration with the National Emergency Laparotomy Audit and is run from across 90 hospitals in England, Wales and Scotland (UK).

When is study starting and how long is it expected to run for?
The study will run from March 2014 until April 2017.

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

Who is the main contact for the study?
Dr Kirsty Everingham
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Study website
http://www.epochtrial.org

Contact information

Type(s)
Scientific

Contact name
Dr Kirsty Everingham

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.1

Study information

Scientific Title
Enhanced Peri-Operative Care for High-risk patients (EPOCH) Trial: A stepped wedge cluster randomised trial of a quality improvement intervention for patients undergoing emergency laparotomy

Acronym
EPOCH

Study objectives
To conduct a large pragmatic clinical trial of the effectiveness of a quality improvement project to implement a modified version of the RCS integrated care pathway to improve patient outcomes following emergency laparotomy and provide the definitive evidence needed to inform practice in this area.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham 1 NRES Committee East Midlands, 26/11/2013, 13/EM/0415

Study design
Multi-centre stepped wedge cluster randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Emergency Laparotomy

Interventions
The EPOCH trial intervention is comprised of a Quality Improvement project to promote implementation of an Integrated Care Pathway for patients undergoing emergency laparotomy

Ninety NHS hospitals will be grouped into fifteen clusters of six on a geographical basis. The quality improvement intervention will commence in one cluster each five week step from the 2nd to the 16th time period, with the order of clusters determined by computer based randomisation. The stepped wedge design allows delivery of the intervention at an organisational level with evaluation of outcome measures at a patient level. Structuring the quality improvement intervention through a staged activation of sites in a random order provides important methodological advantages. The design allows us to control adoption bias and adjust for time-based changes in the background level of patient care in the statistical analysis. A key strength of the stepped wedge design is that we can offer the quality improvement project to every site which takes part.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
All cause mortality at 90 days following surgery

Secondary outcome measures
1. All cause mortality at 180 days following surgery
2. Duration of hospital stay
3. Hospital re-admission within 180 days of surgery
In six hospitals we will collect EQ-5D 3L and healthcare resource use data preoperatively, and at 90 and 180 days post surgery to perform a health economics analysis.

Overall study start date
03/03/2014

Completion date
30/04/2017

Eligibility

Key inclusion criteria
Patients - All patients aged 40 years and over undergoing non-elective open abdominal surgery in participating hospitals during an 85 week period will be eligible for inclusion in the data analysis. The patient inclusion criteria are identical to those of the Healthcare Quality Improvement Partnership National Emergency Laparotomy Audit (HQIP-NELA) and the core EPOCH dataset will only include patient level data gathered by the audit. Hospital sites and clusters - Participating hospitals must undertake a significant volume of emergency laparotomies, participate in the National Emergency Laparotomy Audit, nominate specialty leads from surgery, anaesthesia and critical care, and secure the support from their NHS Trust Board to participate in the EPOCH study. Hospitals which already use an integrated care pathway to maintain standards of care for this patient group will be excluded. Clusters will be organised

geographically with specific attention to the rotation of clinical staff and patient referral patterns between hospitals to minimise contamination of pre-intervention hospitals.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
~27,500 across all sites

Total final enrolment
16000

Key exclusion criteria
The following patients will be excluded:
1. Simple appendicectomy
2. Gynaecological laparotomy
3. Surgery related to organ transplant
4. Laparotomy for traumatic injury
5. Laparotomy to treat complications of recent elective surgery
6. Patients whose data has previously been included in the EPOCH trial

Date of first enrolment
03/03/2014

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Adult Critical Care Research Office (Office 14)
London
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E1 1BB

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
Joint Research Management Office
5 Walden Street
London
England
United Kingdom
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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Health Services and Delivery Research Programme; Ref: 12/5005/10

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/11/2018	23/04/2019	Yes	No

Results article	results	01/06/2019	30/04/2019	Yes	No
Protocol (other)	v2.0	28/04/2014	03/05/2023	No	No
Protocol file	version 2.0	28/04/2014	03/05/2023	No	No
HRA research summary			28/06/2023	No	No