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What is the current standard of post-operative care for patients undergoing emergency abdominal surgery?

Submission date 19/12/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/03/2024	**Overall study status** Completed	
Last Edited 07/08/2024	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
The EMERALD study aims to learn about how people are treated after they have had a type of operation called an “emergency laparotomy.” The team want to understand if the care that people receive after their operation has an impact on how quickly they get better.

Who can participate?
Adult patients aged 18 years old and over who have been diagnosed with a condition that requires an emergency laparotomy.

What does the study involve?
Participants will be asked to complete some questionnaires about their quality of life and how they are feeling. They will be asked to complete these questionnaires when they enter the study and then at 7 days, 30 days, and 90 days after their operation. Relevant information about their health and the care that they receive after their operation will also be collected up until 90 days after their operation; this information will be collected from participants’ standard clinic visits and routine healthcare records so there is nothing extra that participants will need to do.

What are the possible benefits and risks of participating?
There is unlikely to be a direct benefit to the patients who take part in this study. However, the information gained from this study will help identify the best way to care for people after they have had an emergency laparotomy. This may benefit people who are having an emergency laparotomy in the future. There is also no reason to believe that there will be any additional risks to patients if they take part in EMERALD.

Where is the study run from?
The University of Leeds (UK).

When is the study starting and how long is it expected to run for?
March 2021 to January 2025.

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

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
327554

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56174, IRAS 327554

Study information

Scientific Title
Improving outcomes in post-operative emergency laparotomy care - the EMERALD project phase 1: current standards of post-operative care in emergency laparotomy

Acronym
EMERALD Phase 1 Cohort Study

Study objectives
The overall aim of EMERALD is to identify the current standards and variation in EmLap post-operative care across the United Kingdom and their impact on clinical, patient-reported outcomes and health-economic outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/11/2023, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; None provided; Southbirmingham.rec@hra.nhs.uk), ref: 23/WM/0212

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urgent or emergency abdominal surgery (EmLap) on the gastrointestinal tract postoperative care

Interventions
The EMERALD cohort study is a prospective, observational cohort study assessing clinical pathways, processes of care and interventions delivered in the post-operative emergency laparotomy setting and their impact on clinical, patient-reported and health economic outcomes. Patients will be recruited over three months across 25 NHS sites and will be followed up for a period of up to 90 days postoperatively.

Study population
The study will recruit 750 adult patients ≥ 18 years old undergoing expedited, urgent or emergency abdominal surgery (EmLap) on the gastrointestinal tract. Patients undergoing EmLap for trauma, gynaecological conditions or complications of elective surgery will be excluded.

Site eligibility
To be eligible to participate in the trial, research sites must meet the following criteria:
1. Has dedicated emergency surgery services

2. Is contributing to the NELA/ELLSA audits
3. Has the anticipated capacity to recruit a minimum of 10 participants per month

Participant identification and informed consent
Patients will be identified within the emergency general surgical framework at participating centres. Participating centres will be NHS hospitals with dedicated emergency surgery services and contributing to the NELA/ELLSA audits. All patients undergoing EmLap will be screened to assess their eligibility for participation.

Suitability for inclusion into the study will be assessed according to the eligibility criteria by an appropriately qualified member of the patient's healthcare team. Following confirmation of eligibility patients will be approached for possible recruitment into EMERALD by appropriately trained healthcare professionals or research nurses. Approach for participation can be pre-operatively or in the immediate post-operative phase on Day 1 or any day up to and including Day 5 post-operation. Patients will be provided with a verbal explanation of the study by a suitably qualified member of the healthcare team along with an approved Participant Information Sheet (PIS). The PIS will provide detailed information about the rationale, design and personal implications of study participation.

Participants will be provided with an appropriate opportunity to discuss the study with their family and medically qualified members of the healthcare team before they are asked whether they would be willing to take part in the study. Given the emergency nature of EmLap the time available to consider participation will be shorter than in the elective setting, however, patients will be given as long as they need to consider participation into the study. For patients enrolled pre-operatively this will take into the account the time available prior to surgery, ideally this will be at least 2 hours. The right of the patient to refuse consent without giving reasons will be respected.

Assenting patients will then be invited to provide written informed consent for their participation in the trial and formally assessed for eligibility. Informed consent will be obtained by the PI, Associate PI or an appropriate, delegated healthcare professional. The healthcare professional must have knowledge of the study and have received training in the principles of GCP and the Declaration of Helsinki 1996. The healthcare professional must be fully trained in the study according to the ethically approved protocol and be authorised and approved by the PI to take informed consent as documented in the study Authorised Personnel Log (APL).

Registration
Following confirmation of written informed consent and eligibility, patients will be registered into the study by an authorised member of staff at the study site. Registration will be performed centrally using the CTRU automated 24-hour registration system which can be accessed via the web. User ID codes and personal identification numbers (PINs), provided by the CTRU, will be required to access the registration system.

Data collected at registration will include:
- Patient details, including initials and date of birth
- Name and code of the research site
- Name of the person performing the registration
- Confirmation of eligibility
- Confirmation of written informed consent and date
- Date of operation

Data collection
Data will be collected on processes of clinical care, clinical outcomes, patient-reported outcomes (PROs) and health economic data.

Processes of Care: Each participating site will complete a baseline survey outlining the EmLap pathway delivered by each site. This will include the provision and timing of specialist services including dedicated nursing, physiotherapy, dietetics, occupational therapists etc and specific information regarding infrastructure i.e. dedicated ward, emergency general surgeons etc.

Clinical data collection: Clinical data will be collected at baseline (either pre-operatively or in the immediate post-operative period on day 1-5 post-op, depending on when the participant is recruited to the study), and at 30 days post-operation. The majority of this data will be collected through the linkage of routine datasets (NELA/ELLSA). Data on specific clinical outcomes including intra-operative complications, 30-day morbidity, grade of morbidity and 30-day hospital re-operation rates will be collected by local clinical teams.

Informed Consent Documents, Contact Details forms and Serious Adverse Event (SAE)/Related Unexpected Serious Adverse Event (RUSAE) data will be collected via paper case report forms and sent to CTRU via standard post, fax, email or secure file transfer, as appropriate.

All other data collected by site staff will be captured via Remote Data Entry on electronic case report forms in the MACRO study database, managed by the CTRU at the University of Leeds.

Participant-completed data: Participants will complete several questionnaires designed to capture health-related quality of life. Participants will be asked to complete these questionnaires at baseline and 7 days, 30 days and 90 days after their surgery. The baseline questionnaire pack will consist of 2 validated questionnaires and the follow-up questionnaire packs will consist of 3 validated questionnaires.

The baseline quality of life (QoL) questionnaire pack and 7-day post-operative QoL pack will be completed by participants on paper and will be administered to participants by site staff. Participants will be asked to seal their completed questionnaire packs in a pre-supplied envelope before giving it to the local research staff, who will then
post the sealed envelope to the CTRU for entry into the trial database. If it is not possible for the participant to complete the 7-day post-op questionnaires at the site, the local site research team can post the follow-up questionnaires to the participant; in this instance, a stamped, addressed envelope will be provided alongside the
questionnaires so that the participant can post their completed questionnaire pack to the CTRU.

Participants will complete the follow-up questionnaires at home and will have the option to complete these either on paper or online in REDCap. The follow-up questionnaires will be administered directly to participants by the EMERALD CTRU trial team by post, text or email (depending on the participant's QoL-completion preferences). If participants
choose to complete their follow-up questionnaires in paper format via post, a Freepost envelope will be provided so that they can return their completed questionnaire pack to the CTRU. If the participant has chosen to complete their 30/90-day post-op QoL questionnaires on paper but is still in hospital at 30 days post-operation, the 30-day post-
operative questionnaire pack will be administered to the participants by the local research team. Once completed, the participant should seal their questionnaire pack in the envelope provided and return it to a member of the local research team for posting to the CTRU. Should a

completed 30/90 days post-op questionnaire not be received at the
CTRU by the required time-point, the CTRU will send one reminder to the participant either by post, SMS or email (depending on the participant's questionnaire-completion preference).

Routinely collected data: Routine clinical data will be linked with the National Emergency Laparotomy Audit (NELA) and the Emergency Laparotomy and Laparoscopic Scottish Audit (ELLSA) using patients' NHS/CHI number and two other identifiers e.g. date of birth and NELA /ELLSA ID. Routine clinical data will be collected from NELA and ELLSA by the CTRU at baseline and 30 days post-operation.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Intra-operative complications, defined as any adverse event encountered during the operation, measured using data collected from medical records at one time point
2. Post-operative complications, defined as any post-operative complication occurring within 30 days post-operatively, measured using data collected from medical records at one time point. These will be defined in keeping with the Clavien-Dindo classification.
3. Readmission rate, defined as any readmission to hospital within 30 days post-operatively, measured using data collected from medical records at one time point

Key secondary outcome(s))
Quality of Life measured using the Gastrointestinal Quality of Life Index, EQ-5D-5L and the Quality of Recovery-15 score at baseline, 7, 30 and 90 days post-operatively

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Aged > = 18 years old
2. Undergoing expedited, urgent or emergency abdominal surgery (EmLap) on the gastrointestinal tract
3. Be able to provide written informed consent
4. Able and willing to comply with the terms of the protocol
5. Able to read and write English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Undergoing EmLap for trauma, gynaecological conditions or complications of elective surgery
2. Enrolled into an interventional emergency surgery trial e.g. LaCeS2 (the interventional trial should be prioritised)
3. Pre-existing cognitive impairment affecting the patient's capacity to consent

Date of first enrolment
25/06/2024

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes