Understanding the patients that need but do not undergo emergency abdominal surgery

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
11/12/2019		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/01/2020	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
07/10/2024	Surgery			

Plain English summary of protocol

Background and study aims

Older patients (65 years and above) that require, but do not undergo emergency laparotomy (a surgical procedure involving a large incision through the abdominal wall to gain access into the abdominal cavity). NoLAP are an undefined and uncharacterised population. In contrast to those older adults that do undergo emergency surgery, it is not known how many patients constitute this NoLAP group, what characteristics they have, what the reasons are for not undergoing surgery and what their short-term outcomes are. This is the first multi-centred UK study to attempt to answer these questions to try to improve outcomes for the older adult population. The study aims to define the population that needs but does not undergo emergency abdominal surgery.

Who can participate?

Any patient over 65 that needs but does not undergo, emergency abdominal surgery.

What does the study involve?

Patient records will be studies to define this patient population as no-one has looked at this group before. (Age, gender, pathology and decision-making in this patient population).

What are the possible benefits and risks of participating? None

Where is the study run from?

38 sites across the UK with Royal Alexandra Hospital in Paisley as the lead site

When is the study starting and how long is it expected to run for? 27/01/2020 for 18 months

Who is funding the study? Bowel Disease Research Foundation, UK Who is the main contact? Susan Moug, Cl susanmoug@nhs.net

Contact information

Type(s)

Public

Contact name

Miss Susan Moug

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

268511

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Version 2.2, IRAS 268511

Study information

Scientific Title

Defining the Denominator: Emergency Laparotomy and Frailty Study 2

Acronym

ELF 2

Study objectives

Identify a UK consecutive series of older adults presenting with acute abdominal pathology potentially treatable by emergency laparotomy where the decision is made not to undergo surgery (NoLAP) and their associated 90-day mortality.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/11/2019, West Midlands- Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8019; NRESCommittee. WestMidlands-Solihull@nhs.net), ref: 19/WM/0304

Study design

Multi-centre prospective cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Older adults with pathology requiring an emergency laparotomy

Interventions

The study is characterising the number of patients that do not undergo emergency abdominal surgery (age, pathology, diagnosis, gender) and trying to understand the reasons behind that decision not to have emergency surgery. Each patient will be followed up for 30, 90 days after surgery to see if they have died and also at 1 year to see if they have died.

Intervention Type

Procedure/Surgery

Primary outcome(s)

90-day mortality after decision not to undergo emergency laparotomy measured by patient records

Key secondary outcome(s))

The reasoning behind the NOLAP decision measured using patient records at the time

Completion date

10/01/2022

Eligibility

Key inclusion criteria

- 1.65 years or older
- 2. Requires emergency laparotomy for pathology consistent with inclusion into NELA
- 3. Does not undergo emergency laparotomy
- 4. Had review by trained surgeon

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Sex

All

Total final enrolment

750

Key exclusion criteria

- 1. Under 65 years of age
- 2. No surgical review
- 3. Failed conservative management

Date of first enrolment

27/01/2020

Date of final enrolment

27/01/2021

Locations

Countries of recruitment

United Kingdom

England

Scotland

Wales

Study participating centre Royal Alexandra Hospital

Department of Surgery

Paisley United Kingdom PA2 9PN

Study participating centre Wythenshawe Hospital

Manchester University NHS Foundation Trust Southmoore Road Wythenshawe Manchester United Kingdom M23 9QT

Study participating centre Huddersfield Royal Infirmary

Calderdale and Huddersfield NHS Foundation Trust Huddersfield United Kingdom HD3 3EA

Study participating centre Pinderfields Hospital

Aberford Road Wakefield United Kingdom WF1 4DG

Study participating centre East Surrey Hospital

Surrey And Sussex Healthcare NHS Trust Canada Avenue Redhill United Kingdom RH1 5RH

Study participating centre Whiston Hospital

Prescot United Kingdom L35 5DR

Study participating centre Borders General Hospital

Melrose United Kingdom TD6 9BS

Study participating centre York Hospital Wigginton Road

York United Kingdom YO31 8HE

Study participating centre Forth Valley Royal Hospital

Larbert United Kingdom FK5 4WR

Study participating centre Queen Elizabeth University Hospital

Glasgow United Kingdom G51 4TF

Study participating centre Royal Gwent Hospital

Newport United Kingdom NP20 2UB

Study participating centre Medway Maritime Hospital

Gillingham United Kingdom ME7 5NY

Study participating centre Dumfries and Galloway Royal Infirmary

Cargenbridge United Kingdom DG2 8RX

Study participating centre Royal Bolton Hospital

Bolton United Kingdom BL4 0JR

Study participating centre The Royal London Hospital

London United Kingdom E1 1FR

Study participating centre Glasgow Royal Infirmary

Glasgow United Kingdom G4 0SF

Study participating centre Musgrove Park Hospital

Taunton United Kingdom TA1 5DA

Study participating centre Blackpool Victoria Hospital

Blackpool United Kingdom FY3 8NR

Study participating centre Glangwili General Hospital

Carmarthen

United Kingdom SA31 2AF

Study participating centre
Norfolk & Norwich University
Norwich
United Kingdom
NR4 7UY

Study participating centre
Aintree University Hospital
Liverpool
United Kingdom
L9 7AL

Study participating centre Countess Of Chester Hospital Chester United Kingdom CH2 1HJ

Study participating centre Bristol Royal Infirmary Bristol United Kingdom BS2 8HW

Study participating centre St Thomas' Hospital London United Kingdom SE1 7EH

Study participating centre New Cross Hospital Wolverhampton United Kingdom WV10 0QP

Study participating centre Royal Derby Hospital

Derby United Kingdom DE22 3NE

Study participating centre
University Hopsital of Wales
Cardiff
United Kingdom
CF14 4XW

Study participating centre Tunbridge Wells Hospital Tunbridge Wells United Kingdom TN2 4QJ

Study participating centre Weston General Hospital Weston-super-Mare United Kingdom BS23 4TQ

Study participating centre
Royal Devon and Exeter Hospital
Exeter
United Kingdom
EX2 5DW

Study participating centre Morriston Hospital Swansea United Kingdom SA6 6NL

Study participating centre

University Hospital Ayr

Ayr United Kingdom KA6 6DX

Study participating centre Wrexham Maelor Hospital

Wrexham United Kingdom LL13 7TD

Study participating centre Aberdeen Royal Infirmary

Aberdeen United Kingdom AB25 2ZN

Study participating centre Raigmore Hospital

Inverness United Kingdom IV2 3UJ

Study participating centre Western General Hospital

Edinburgh United Kingdom EH4 2XU

Sponsor information

Organisation

NHS Greater Glasgow and Clyde

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type

Research organisation

Funder Name

Bowel Disease Research Foundation

Alternative Name(s)

BDRF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/09/2024	07/10/2024	Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.2	21/08/2019	16/08/2022	No	No