ISRCTN14556210 https://doi.org/10.1186/ISRCTN14556210

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

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

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
268511

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

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

Overall study start date

01/06/2019

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

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
700

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
England

Scotland

United Kingdom

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

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maureen.travers@ggc.scot.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nhsggc.org.uk/about-us/professional-support-sites/research-development/rd-management-office/#

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/01/2021

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?
Protocol file	version 2.2	21/08/2019	16/08/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		19/09/2024	07/10/2024	Yes	No