

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

<b>Submission date</b> 11/12/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/10/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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 studied 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  
susanmoug@nhs.net

## Contact information

### Type(s)

Public

### Contact name

Miss Susan Moug

### ORCID ID

<http://orcid.org/0000-0001-9969-9760>

### Contact details

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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 Hospital 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**  
**Morrison 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

### **Sponsor details**

Dykebar Hospital, Grahamston Road  
Paisley  
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United Kingdom  
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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?
<a href="#">Protocol file</a>	version 2.2	21/08/2019	16/08/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		19/09/2024	07/10/2024	Yes	No