

# A clinical trial of blood flow optimisation for patients who have emergency bowel surgery

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>10/04/2017   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>02/05/2017 | <b>Overall study status</b><br>Ongoing            | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>14/08/2025       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Emergency bowel surgery (laparotomy) is a major procedure which can lead to reduced blood flow to vital organs. This can lead to complications after surgery. Fluids are given into the bloodstream (intravenous) to improve blood flow. Giving the right amount of this intravenous fluid at the right time is important for recovery after surgery, but is hard to gauge accurately. Doctors normally use signs such as heart rate and blood pressure to guide them, but these can be unreliable. Previous research has shown that a treatment used during surgery and shortly afterwards may improve the amount of oxygen delivered to the body's tissues and reduce the number of patients who develop complications after surgery. This treatment involves using a heart monitor (cardiac output monitor) to help clinical teams decide the amount and timing of intravenous fluid to give to patients. There is some evidence from smaller studies that this treatment is beneficial, but this needs to be confirmed in a much larger study. The aim of this study is to find out whether the use of cardiac output monitoring to guide the use of intravenous fluid increases the number of days spent alive and out of hospital within 90 days of randomisation compared with usual care.

### Who can participate?

Patients aged 50 years and over undergoing emergency laparotomy

### What does the study involve?

During and after surgery, participants are randomly allocated to receive one of the treatments, either the study treatment or usual care. Participants' experiences are the same regardless of which treatment they receive, and they probably won't be able to tell which one they are getting. Both treatments begin at the start of surgery and finish six hours after it has ended. The two treatments involve slightly different ways of deciding the amount of intravenous fluid participants receive. If they receive usual care their doctor uses measurements such as heart rate and blood pressure to guide this. If they receive the new study treatment their clinical team also measures the amount of blood their heart pumps each minute using an extra monitor. These extra measurements help the doctor to decide how much intravenous fluid they give. After the treatment is over, care continues as normal and there is no need to contact the participants further. Routinely collected information from medical notes and NHS databases is used to follow-up participants' recovery after surgery.

What are the possible benefits and risks of participating?  
Previous research suggests that the treatment is safe and should benefit most patients.  
Participants are closely monitored throughout the study and, if necessary, their clinical team makes adjustments to their treatment to make sure they are safe.

Where is the study run from?  
50 hospitals in the UK, led by Southampton General Hospital

When is the study starting and how long is it expected to run for?  
May 2017 to December 2025

Who is funding the study?  
Health Technology Assessment Programme (UK)

Who is the main contact?  
Zoe Clark, admin@floela.org

**Study website**  
<http://www.floela.org>

## Contact information

**Type(s)**  
Public

**Contact name**  
Ms Zoe Clark

**Contact details**  
Research and Development  
Southampton Centre for Biomedical Research  
University Hospital Southampton NHS Foundation Trust  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD  
+44 (0)23 8120 1863  
zoe.clark@uhs.nhs.uk

**Type(s)**  
Scientific

**Contact name**  
Prof Mark Edwards

**ORCID ID**  
<https://orcid.org/0000-0002-5048-1784>

**Contact details**

University Hospital Southampton  
Southampton  
United Kingdom  
SO16 6YD  
-  
admin@floela.org

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**  
214459

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
CRI0336; HTA 15/80/54

## Study information

### Scientific Title

FLuid Optimisation in Emergency LAParotomy (FLO-ELA): an open, multi-centre, randomised controlled trial of cardiac output-guided haemodynamic therapy compared to usual care in patients undergoing emergency bowel surgery

### Acronym

FLO-ELA

### Study objectives

To establish whether the use of minimally invasive cardiac output monitoring to guide protocolised administration of intra-venous fluid (goal-directed haemodynamic therapy, GDHT), for patients aged 50 and over undergoing emergency laparotomy will reduce mortality within 90 days of randomisation, when compared with usual care.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

London - Bromley Research Ethics Committee, 28/03/2017, ref: 17/LO/0334

### Study design

Randomized controlled trial with open study group allocation and internal pilot study, supported by ongoing data collection from the National Emergency Laparotomy Audit (NELA)

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See study outputs table

**Health condition(s) or problem(s) studied**

Surgery - emergency laparotomy

**Interventions**

The trial treatment period will commence at the start of general anaesthesia and continue for six hours after the completion of surgery. Eligible patients will be randomised to receive either cardiac-output guided haemodynamic therapy (intervention group), or usual care (control group). Perioperative management for all patients during the trial treatment period will be in accordance with recommended guidance.

Intervention: Treatment algorithm guided by cardiac output monitoring to determine dose and timing of intravenous fluid. Clinicians may choose from a range of cardiac output monitors in established use which have been shown to track changes in cardiac stroke volume accurately. 250ml aliquots of crystalloid or colloid solution will be administered according to the algorithm to achieve and maintain an optimal value of stroke volume. This intervention supplements but does not replace the monitoring used for conventional clinical assessments. The protocol allows the treating clinician to adjust the volume and type of fluid administered, e.g. if there is concern about persistent hypovolaemia or fluid overload.

Control: Usual care, with intravenous fluid given according to conventional clinical assessment without the use of cardiac output monitoring or algorithm.

**Intervention Type**

Other

**Primary outcome measure**

Current primary outcome measure as of 23/12/2021:

Days Alive and Out of Hospital within 90 days of randomisation (DAOH-90)

---

Previous primary outcome measure:

Mortality within 90 days of randomisation, using mortality data from NHS Digital/Office for National Statistics (or equivalents)

**Secondary outcome measures**

Current secondary outcome measures as of 23/12/2021:

Mortality within 90 days of randomisation, using mortality data from NHS Digital/Office for National Statistics (or equivalents)

Process outcomes:

1. Duration of hospital stay, from data entered into the National Emergency Laparotomy Audit (NELA) by teams in each participating hospital
2. Duration of stay in a critical care bed within the primary hospital admission, from data entered into NELA by teams in each participating hospital
3. Hospital readmission as an inpatient (overnight stay) within 90 days from randomisation, using data from NHS Digital/Hospital Episode Statistics (or equivalents)

Health economic endpoints:

1. Mean cost of implementing the intervention and control treatments
2. Mean cost of secondary care resource use within 90 days from randomisation
3. Quality-adjusted life year gain at 90 days from randomisation using EQ-5D-3L-derived utility scores at baseline and 90 day follow-up (estimated from preceding EPOCH trial data – no EQ-5D-3L data collection will be required within the FLO-ELA trial)

---

Previous secondary outcome measures:

Mortality within one year of randomisation, using mortality data from NHS Digital/Office for National Statistics (or equivalents)

Process outcomes:

1. Duration of hospital stay, from data entered into the National Emergency Laparotomy Audit (NELA) by teams in each participating hospital
2. Duration of stay in a critical care bed within the primary hospital admission, from data entered into NELA by teams in each participating hospital
3. Hospital readmission as an inpatient (overnight stay) within 90 days from randomisation, using data from NHS Digital/Hospital Episode Statistics (or equivalents)

Health economic endpoints:

1. Mean cost of implementing the intervention and control treatments
2. Mean cost of secondary care resource use within 90 days from randomisation
3. Quality-adjusted life year gain at 90 days from randomisation using EQ-5D-3L-derived utility scores at baseline and 90 day follow-up (estimated from preceding EPOCH trial data – no EQ-5D-3L data collection will be required within the FLO-ELA trial)

**Overall study start date**

01/05/2017

**Completion date**

31/12/2025

## Eligibility

**Key inclusion criteria**

1. Age 50 years and over
2. Scheduled to undergo a surgical procedure which fulfils the criteria for entry into the National

Emergency Laparotomy Audit (NELA), i.e. an expedited, urgent or emergency abdominal procedure on the gastrointestinal tract within the audit scope, including:

- 2.1. Procedures involving the stomach, small or large bowel, or rectum for conditions such as perforation, ischaemia, abdominal abscess, bleeding or obstruction
  - 2.2. Washout/evacuation of intra-peritoneal abscess (unless due to appendicitis or cholecystitis)
  - 2.3. Bowel resection/repair due to incarcerated umbilical, inguinal and femoral hernias (but not hernia repair without bowel resection/repair)
  - 2.4. Return to theatre for repair of substantial dehiscence of major abdominal wound (i.e. 'burst abdomen') or after patients underwent non-elective gastro-intestinal surgery
3. Patient has an NHS number

The term "emergency" laparotomy is defined in line with NELA and the National Confidential Enquiry into PeriOperative Deaths (NCEPOD) 2004, to encompass the following categories: "immediate" surgery (required within two hours of the decision to operate), "urgent" surgery (required within 2-18 hours of the decision to operate) and "expedited" surgery (required within 18-24 hours of the decision to operate)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

50 Years

### **Sex**

Both

### **Target number of participants**

3138

### **Total final enrolment**

3138

### **Key exclusion criteria**

1. Refusal of patient consent
2. Clinician refusal
3. Previous enrolment in the FLO-ELA trial
4. Previous inclusion in NELA within the current hospital admission
5. Current participation in another clinical trial of a treatment with a similar biological mechanism
6. Scheduled abdominal procedure outside the scope of NELA, including: elective procedures, uncomplicated appendicectomy or cholecystectomy, non-elective hernia repair without bowel resection, vascular surgery, including abdominal aortic aneurysm repair, Caesarean section, obstetric laparotomies or gynaecological laparotomy, or laparotomy/laparoscopy for pathology caused by trauma

### **Date of first enrolment**

01/07/2017

### **Date of final enrolment**

28/11/2024

# Locations

## **Countries of recruitment**

England

Scotland

United Kingdom

Wales

## **Study participating centre**

### **University Hospital Southampton**

Southampton University Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

## **Study participating centre**

### **Russells Hall Hospital**

Pensnett Road

Dudley

United Kingdom

DY1 2HQ

## **Study participating centre**

### **Derriford Hospital**

Derriford Road

Derriford

Plymouth

United Kingdom

PL6 8DH

## **Study participating centre**

### **Royal Free Hospital**

London

United Kingdom

NW3 2QG

**Study participating centre**  
**Medway Maritime Hospital**  
Gillingham  
United Kingdom  
ME7 5NY

**Study participating centre**  
**Harrogate District Hospital**  
Harrogate  
United Kingdom  
HG2 7SX

**Study participating centre**  
**Warwick Hospital**  
Warwick  
United Kingdom  
CV34 5BW

**Study participating centre**  
**Sherwood Forest Hospitals**  
Mansfield  
United Kingdom  
NG17 4JL

**Study participating centre**  
**Torbay Hospital**  
Torbay  
United Kingdom  
TQ2 7AA

**Study participating centre**  
**Conquest Hospital**  
St Leonards-on-Sea  
United Kingdom  
TN37 7PT

**Study participating centre**  
**King's Mill Hospital**  
Mansfield Rd



Sutton-in-Ashfield  
United Kingdom  
NG17 4JL

**Study participating centre**  
**Watford General Hospital**  
Vicarage Road  
Watford  
United Kingdom  
WD18 0HB

**Study participating centre**  
**St Thomas' Hospital**  
Westminster Bridge Rd  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**St James University Hospital NHS Trust**  
St James's University Hospital  
Gledow Wing  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**  
**University Hospital Birmingham**  
Queen Elizabeth Hospital  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TH

**Study participating centre**  
**Royal London Hospital and Associated Community Services NHS Trust**  
The Royal London Hospital  
Whitechapel

London  
United Kingdom  
E1 1BB

**Study participating centre**  
**The Royal Victoria Infirmary**  
Queen Victoria Road  
Newcastle upon Tyne  
United Kingdom  
TS1 4LP

**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**University Hospital Lewisham**  
Lewisham High Street  
London  
United Kingdom  
SE13 6LH

**Study participating centre**  
**Mersey Care NHS Trust at Aintree Hospital**  
C/o University Hospital Aintree  
Fazakerley Hospital  
Lower Lane  
Liverpool  
United Kingdom  
L9 7AL

**Study participating centre**  
**Queens Hospital**  
Belvedere Road  
Burton-on-trent  
United Kingdom  
DE13 0RB

**Study participating centre**  
**Croydon University Hospital**  
London Road  
Croydon  
United Kingdom  
CR7 7YE

**Study participating centre**  
**Royal Bournemouth General Hospital**  
Castle Lane East  
Bournemouth  
United Kingdom  
BH7 7DW

**Study participating centre**  
**Royal Derby Hospital**  
Uttoxeter Road  
Derby  
United Kingdom  
DE22 3NE

**Study participating centre**  
**Southport District General Hospital**  
Town Lane  
Kew  
Southport  
United Kingdom  
PR8 6NJ

**Study participating centre**  
**University Hospital of North Durham**  
University Hospital of Durham  
Dryburn Hospital  
North Road  
Durham  
United Kingdom  
DH1 5TW

**Study participating centre**

**Royal United Hospitals Bath NHS Foundation Trust**  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**Southmead Hospital**  
Southmead Road  
Westbury-on-trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**  
**St George's at Kings College Hospital**  
Denmark Hill  
London  
United Kingdom  
SE5 9RS

**Study participating centre**  
**Northwick Park and St Marks NHS Trust**  
Northwick Park Hospital  
Watford Road  
Harrow  
United Kingdom  
HA1 3UJ

**Study participating centre**  
**William Harvey Hospital**  
Kennington Road  
Willesborough  
Ashford  
United Kingdom  
TN24 0LZ

**Study participating centre**  
**Norfolk & Norwich University Hospital**  
Colney Lane  
Colney

Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**

**Queens Hospital**

Rom Valley Way  
Romford  
United Kingdom  
RM7 0AG

**Study participating centre**

**Worcestershire Royal Hospital**

Charles Hastings Way  
Worcester  
United Kingdom  
WR5 1DD

**Study participating centre**

**Royal Shrewsbury Hospital**

Mytton Oak Road  
Shrewsbury  
United Kingdom  
SY3 8XQ

**Study participating centre**

**University Hospital of Wales**

Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**

**Manchester Royal Royal Infirmary**

Cobbett House  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Whipps Cross Hospital**  
Whipps Cross Road  
London  
United Kingdom  
E11 1NR

**Study participating centre**  
**Victoria Hospital**  
Hayfield Road  
Kirkcaldy  
United Kingdom  
KY2 5AH

## **Sponsor information**

**Organisation**  
University Hospital Southampton NHS Foundation Trust

**Sponsor details**  
Southampton General Hospital  
Tremona Road  
Southampton  
England  
United Kingdom  
SO16 6YD

**Sponsor type**  
Hospital/treatment centre

**ROR**  
<https://ror.org/0485axj58>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Current publication and dissemination plan as of 13/08/2025:

1. Final Report to funder - July 2026
2. Planned publication in a high-impact peer-reviewed journal - summer 2026
3. Conferences and meetings - 2026 - ongoing

Previous publication and dissemination plan as of 23/12/2021:

1. Final Report to funder - January 2024
2. Planned publication in a high-impact peer-reviewed journal - summer 2024
3. Conferences and meetings - 2024 - ongoing

Previous publication and dissemination plan:

1. Final Report to funder - March 2022
2. Planned publication in a high-impact peer-reviewed journal - summer 2022
3. Conferences and meetings - 2022 - ongoing

**Intention to publish date**

31/01/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from [admin@floela.org](mailto:admin@floela.org). Any data sharing requests will be subject to the Pragmatic Clinical Trials Unit data sharing policy.

**IPD sharing plan summary**

Available on request

**Study outputs**

| Output type                                   | Details      | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|--------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | version V6.0 | 01/07/2020   | 21/07/2020 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version V2.0 | 29/04/2020   | 21/07/2020 | No             | No              |
| <a href="#">Protocol file</a>                 | version 3.0  | 22/09/2021   | 23/03/2022 | No             | No              |
|   | version 4.0  |              |            |                |                 |

|                                      |             |            |            |     |    |
|--------------------------------------|-------------|------------|------------|-----|----|
| <a href="#">Protocol file</a>        |             | 27/04/2022 | 24/05/2022 | No  | No |
| <a href="#">Protocol article</a>     |             | 06/05/2023 | 09/05/2023 | Yes | No |
| <a href="#">HRA research summary</a> |             |            | 28/06/2023 | No  | No |
| <a href="#">Protocol file</a>        | version 5.0 | 14/11/2024 | 06/08/2025 | No  | No |