ISRCTN14729158 https://doi.org/10.1186/ISRCTN14729158

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

Submission date
10/04/2017

Recruitment status
No longer recruiting

Registration date
02/05/2017

Overall study status
Completed

Last Edited
06/11/2025

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
214459

Protocol serial number
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
Current study objectives as of 06/11/2025:
To establish whether the use of minimally invasive cardiac output monitoring to guide protocolised administration of intravenous fluid (goal-directed haemodynamic therapy [GDHT]), for patients aged 50 years and over undergoing emergency laparotomy will increase the number of days spent alive and out of hospital within 90 days of randomisation, when compared with usual care.

Previous study objectives:
To establish whether the use of minimally invasive cardiac output monitoring to guide protocolised administration of intravenous fluid (goal-directed haemodynamic therapy [GDHT]), for patients aged 50 years 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

Study type(s)
Treatment

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 6 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. 250 ml 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(s)
Current primary outcome measure as of 23/12/2021:

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

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Previous primary outcome measure:

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

Key secondary outcome(s))
Current secondary outcome measures as of 05/11/2025:
1. Mortality within 90 days of randomisation
2. Mortality within 1 year of randomisation
Measured 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)

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Previous 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)

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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)

Completion date

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

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
United Kingdom

England

Scotland

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
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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
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BA1 3NG

Study participating centre
Southmead Hospital
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Westbury-on-trym
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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
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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
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United Kingdom
WR5 1DD

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
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SY3 8XQ

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University Hospital of Wales
Heath Park
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CF14 4XW

Study participating centre
Manchester Royal Royal Infirmary
Cobbett House

Oxford Road
Manchester
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M13 9WL

Study participating centre
Whipps Cross Hospital
Whipps Cross Road
London
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E11 1NR

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
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KY2 5AH

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

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 available upon request from 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?
Protocol article		06/05/2023	09/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V6.0	01/07/2020	21/07/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V2.0	29/04/2020	21/07/2020	No	No
Protocol file	version 3.0	22/09/2021	23/03/2022	No	No
Protocol file	version 4.0	27/04/2022	24/05/2022	No	No
Protocol file	version 5.0	14/11/2024	06/08/2025	No	No
Statistical Analysis Plan	version 5.0	21/10/2025	05/11/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes