

# CAMELOT - Continuous rectus sheath Analgesia in eMErgency LaparOTomy

<b>Submission date</b> 04/08/2022	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/08/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/09/2023	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In the UK around 30,000 patients, a year undergo an operation called an emergency laparotomy to treat life-threatening conditions. A large vertical cut is made in the abdomen when patients are asleep under general anesthesia. Good pain relief after surgery will help patients feel better and recover quicker. Because of the high level of pain experienced by many patients, opioid-based painkillers such as morphine are often given, using patient-controlled analgesia (PCA) pumps. However, morphine can cause serious side effects such as breathing problems, nausea and vomiting, and delayed bowel movement, which can slow patient recovery. Rectus sheath catheters (RSCs) are a newer way of providing pain relief, where two thin tubes (catheters) are inserted on either side of the wound during the operation. Local anesthetic is injected slowly into the catheters to numb the nerves and reduce pain for about three days. Small studies suggest that RSCs may provide effective pain relief, reduce the use of morphine, and help patient recovery. Potential disadvantages are that RSCs take time to insert and are expensive. More work is needed to understand whether there are any unwanted effects with RSCs.

This study will find out whether adding a RSCs to standard patient-controlled analgesia provides better pain relief, fewer side effects and complications, and greater satisfaction for patients undergoing emergency laparotomy compared to a control group who will receive a sham catheter with no infusion of analgesia. Our study will also aim to determine whether RSCs are safe and cost-effective.

### Who can participate?

Adults who are due to undergo emergency laparotomy surgery.

### What does the study involve?

Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). An active Rectus Sheath Catheter (RSC) with a constant infusion of local anesthesia for 72 h from the end of surgery will be given to one group of participants. The other group will receive a sham rectus sheath catheter with an inactive infusion device in place for 72 h from the end of surgery. Participants and researchers will not have a choice in which of the two treatments will be given to each participant and will not know which treatment participants have received during the study.

What are the possible benefits and risks of participating?

The benefits of the CAMELOT study are that we hope that patients will have less pain after their operation and that their recovery/discharge time may be quicker.

The risks for participating in the CAMELOT study are associated with the 'active' rectus sheath catheter and are extremely rare. Participants will be actively monitored throughout the study for any possible side effects. Some of the rare risks are described below:

1. Disconnection. Occasionally the RSCs may become accidentally disconnected from the pump. If this happens, we will remove the RSCs to prevent infection, and you will be able to have other forms of pain relief.
2. Infection. This will be actively monitored by the participant's clinician who will treat accordingly and remove the RSC.
3. Bleeding. This will be actively monitored by the participant's clinician who will treat accordingly and remove the RSC.

Where is the study run from?

University Hospital Southampton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

From January 2022 to October 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?

Jonathan Evans, camelot-trial@bristol.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Mr Jonathan Evans

### Contact details

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## Additional identifiers

EudraCT/CTIS number

Nil known

**IRAS number**

312553

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 312553, Sponsor Number: CRI0420, Funder ID: NIHR133554, CPMS 53589

## Study information

**Scientific Title**

CAMELOT - Continuous rectus sheath Analgesia in eMERgency LaparOTomy. A Multi-centre, randomised sham-controlled trial of rectus sheath catheter-delivered local anaesthetic infusion compared with usual care in patients undergoing emergency bowel surgery.

**Acronym**

CAMELOT

**Study objectives**

The use of a rectus sheath catheter (RSC)-delivered local anaesthetic infusion in addition to standard analgesia, is superior to standard analgesia without RSC for postoperative pain control.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 24/08/2022, London - Bromley Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)207 104 8105; bromley.rec@hra.nhs.uk), ref: 22/LO/0555

**Study design**

Multi-centre, double-blind, pragmatic, parallel-group, superiority randomized sham-controlled trial with an internal pilot phase to determine feasibility of recruitment and protocol adherence

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a participant information sheet

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

Use of rectus sheath catheters (RSCs) in patients undergoing emergency bowel surgery.

### **Interventions**

CAMELOT is a multi-centre, pragmatic, randomised controlled trial in NHS hospitals, with a 12-month internal pilot phase and active follow-up for 6 months post-surgery.

Patients who are undergoing an emergency laparotomy surgery via a midline incision and eligible for inclusion in the National Emergency

Laparotomy Audit (NELA) will be randomised after their midline incision has been performed and before the start of surgical closure, using a secure internet-based randomisation system ensuring allocation concealment. Participants will be allocated into one of two groups via a 1:1 ratio:

1. Insertion of an active RSC with infusion of standard local analgesia for 72 hours from the end of surgery
2. A sham RSC, placed on the skin of surgical site by adhesive dressing and not delivering any local anaesthetic for 72 hours, from the end of surgery

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

Postoperative pain control measured using the Overall Benefit of Analgesia Score (OBAS) over the first 5 postoperative days

### **Secondary outcome measures**

1. Postoperative complications measured using the incidence of the following postoperative complications with severity of Clavien-Dindo grade II or higher collected in the CRF/patient records within 30-days of randomisation:
  - 1.1. Postoperative pulmonary complications (PPC)
  - 1.2. Respiratory failure
  - 1.3. Paralytic ileus
  - 1.4. Incisional surgical site infection
  - 1.5. Rectus sheath catheter/infusion-related complications
2. Time to tracheal extubation (in days) measured using data collected in the CRF/patient records between randomisation and the day of tracheal extubation
3. Time to return of bowel function (in days) measured using data collected in the CRF/patient records between randomisation and the day of the return of bowel function
4. Time to first mobilisation (in days) measured using data collected in the CRF/patient records between randomisation and the day of first mobilisation
5. Pain intensity at rest and on movement measured using data collected in the CRF/patient records on postoperative days 1, 2, 3, 4, and 5
6. Postoperative opioid use measured using data collected in the CRF/patient records in the first five days from the end of surgery
7. Mortality measured using the incidence of death collected in the CRF/patient records at 30 and 90 days from the date of randomisation
8. Chronic postoperative pain measured using the Brief Pain Inventory at 3 and 6 months from the date of randomisation

9. Health-related quality of life measured using the EQ5D-5L at 3 days, and 3 and 6 months from the date of randomisation
10. Return to work and activity measured using the Work Productivity and Activity Impairment Questionnaire: General Health (WPAI:GH) at 3 and 6 months from the date of randomisation

**Overall study start date**

22/01/2022

**Completion date**

26/10/2026

## Eligibility

**Key inclusion criteria**

1. Aged  $\geq 18$  years
2. Undergoing emergency laparotomy surgery via a midline incision
3. Eligible for inclusion in the National Emergency Laparotomy Audit (NELA)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

750

**Key exclusion criteria**

Current participant exclusion criteria:

1. Planned epidural anaesthesia
2. Clinician refusal
3. Lack of mental capacity to consent to trial participation
4. Contraindications to RSC including allergy to local anaesthetic (LA), anatomical factors making RSC insertion impossible
5. Existing co-enrolment in another clinical study if:
  - 5.1. The intervention in the other study is expected to influence the primary outcome (this will be considered by a senior clinician on a case-by-case basis)
  - 5.2. It is considered too burdensome for the patient; or
  - 5.3. It is not permitted by the other study
6. Previous enrolment in the CAMELOT trial

Previous participant exclusion criteria:

1. Clinician or patient refusal to participate
2. Planned epidural anaesthesia

3. Contraindications to Rectus Sheath Catheter (RSC) including allergy to local anaesthetic (LA)
4. Anatomical factors making RSC insertion impossible

**Date of first enrolment**

25/01/2023

**Date of final enrolment**

01/09/2025

## **Locations**

**Countries of recruitment**

England

Scotland

United Kingdom

**Study participating centre**

**North Bristol NHS Trust**

Southmead Hospital

Southmead Road

Westbury-on-trym

Bristol

United Kingdom

BS10 5NB

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**

St. James's University Hospital

Beckett Street

Leeds

United Kingdom

LS9 7TF

**Study participating centre**

**Medway NHS Foundation Trust**

Medway Maritime Hospital

Windmill Road

Gillingham

United Kingdom

ME7 5NY

**Study participating centre**  
**Musgrove Park Hospital**  
Musgrove Park  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**  
**Royal Alexandra Hospital**  
Corsebar Road  
Paisley  
United Kingdom  
PA2 9PN

**Study participating centre**  
**Barts Health NHS Trust**  
The Royal London Hospital  
80 Newark Street  
London  
United Kingdom  
E1 2ES

**Study participating centre**  
**The Dudley Group NHS Foundation Trust**  
Russells Hall Hospital  
Pensnett Road  
Dudley  
United Kingdom  
DY1 2HQ

**Study participating centre**  
**Blackpool Teaching Hospitals NHS Foundation Trust**  
Victoria Hospital  
Whinney Heys Road  
Blackpool  
United Kingdom  
FY3 8NR

**Study participating centre**  
**City Hospitals Sunderland NHS Foundation Trust**  
Sunderland Royal Hospital

Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Great Western Hospitals NHS Foundation Trust**  
Great Western Hospital  
Marlborough Road  
Swindon  
United Kingdom  
SN3 6BB

**Study participating centre**  
**University Hospitals Birmingham NHS Foundation Trust**  
Queen Elizabeth Hospital  
Mindelsohn Way  
Edgbaston  
Birmingham  
United Kingdom  
B15 2GW

**Study participating centre**  
**The Royal Wolverhampton NHS Trust**  
New Cross Hospital  
Wolverhampton Road  
Heath Town  
Wolverhampton  
United Kingdom  
WV10 0QP

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

**Study participating centre**  
**Royal Liverpool University Hospital NHS Trust**  
Royal Liverpool University Hospital



Prescot Street  
Liverpool  
United Kingdom  
L7 8XP

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

**Study participating centre**  
**York Hospitals NHS Trust Hq**  
York Hospital  
Wigginton Road  
York  
United Kingdom  
YO31 8HE

**Study participating centre**  
**Manchester University NHS Foundation Trust**  
Cobbett House  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Ayrshire Central Hospital**  
Kilwinning Road  
Irvine  
United Kingdom  
KA12 8SS

**Study participating centre**  
**NHS Greater Glasgow and Clyde**  
J B Russell House  
Gartnavel Royal Hospital  
1055 Great Western Road Glasgow  
Glasgow

United Kingdom  
G12 0XH

**Study participating centre**

**South Tees Hospitals NHS Trust**  
Middlesbrough General Hospital  
Ayresome Green Lane  
Middlesbrough  
United Kingdom  
TS5 5AZ

**Study participating centre**

**Heartlands Hospital**  
Bordesley Green East  
Bordesley Green  
Birmingham  
United Kingdom  
B9 5ST

**Study participating centre**

**Medway NHS Foundation Trust**  
Medway Maritime Hospital  
Windmill Road  
Gillingham  
United Kingdom  
ME7 5NY

## **Sponsor information**

**Organisation**

University Hospital Southampton NHS Foundation Trust

**Sponsor details**

R&D Department  
University Hospital Southampton NHS Foundation Trust  
Level E, Laboratory & Pathology Block  
SCBR - Mailpoint 138  
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Southampton  
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+44 (0)2381205146  
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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uhs.nhs.uk/home.aspx>

**ROR**

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

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health and Care Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**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

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

26/10/2026

## Individual participant data (IPD) sharing plan

Data will not be made available for sharing until after publication of the main results of the study unless agreed by the Chief Investigator/Trial Management Group on a case-by-case basis. Thereafter, anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Sharing regarding scientific quality, ethical requirements, and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods, and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. Please contact Mark Edwards using the following email: camelot-trial@bristol.ac.uk.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 1.0	01/07/2022	22/12/2022	No	No
<a href="#">Protocol file</a>	version 2.0	12/04/2023	03/05/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No