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CAMELOT - Continuous rectus sheath Analgesia in eMErgency LaparOTomy

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Registration date 09/08/2022	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 04/09/2023	**Condition category** Surgery	[ ] Individual participant data [ ] 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. Particpiants 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

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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 ≥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
Tremona Road
Southampton
England
United Kingdom

SO16 6YD
+44 (0)2381205146
sharon.davies-dear@uhs.nhs.uk

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?
Protocol file	version 1.0	01/07/2022	22/12/2022	No	No
Protocol file	version 2.0	12/04/2023	03/05/2023	No	No
HRA research summary			28/06/2023	No	No