ISRCTN52352431 https://doi.org/10.1186/ISRCTN52352431

Does intravenous lidocaine speed up gut recovery after large bowel surgery?

Submission date 13/06/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/06/2018	**Overall study status** Completed	
Last Edited 27/01/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
A common problem in about 40% of patients having colorectal (large bowel) surgery is that their gut takes longer than normal to start working again. In most patients the gut will start working after surgery in 2-3 days, but in some it takes a week or more. This delayed recovery causes nausea, vomiting, complete constipation, tummy pain and tummy swelling and can take days to improve. During this time patients have to stay in hospital with a continuous intravenous drip and often need insertion of a nasogastric tube to empty the stomach to reduce vomiting (most patients find this very unpleasant).
Lidocaine (a local anaesthetic) used intravenously (through the vein) has been shown to reduce pain and inflammation after surgery and seems to help other aspects of recovery that may be important for return of gut function, for example reducing nausea and vomiting.
The ALLEGRO study hopes to find out if lidocaine can help improve the recovery of gut function in patients after bowel surgery. Half of the people who agree to take part in ALLEGRO will receive the intravenous lidocaine and half will receive a placebo (or dummy) salt solution intravenously. We will then compare the two groups and see whether gut function returns more quickly in the group who have received intravenous lidocaine

Who can participate?
Adults having certain types of surgery to their colon or rectum (large bowel).

What does the study involve?
Participants will be randomly allocated to receive intravenous lidocaine or placebo salt solution continuously for 6-12 hours starting at the start of general anaesthesia. They will undergo the planned surgery and aftercare as normal.

What are the possible benefits and risks of participating?
We hope that intravenous lidocaine may help to prevent gut problems after surgery, leading to faster recovery and discharge from hospital. However, there may be no medical benefit to you from participation in this study. This study will help to determine whether intravenous lidocaine can help gut recovery in patients having bowel surgery. The information we get from this study may help us to improve treatment of future patients requiring bowel surgery.
It is not thought that there are any disadvantages of taking part in this research study. You are

undergoing scheduled bowel surgery. Any bowel surgery has possible risks and discomforts. Your doctor will explain these risks to you. Participation in the ALLEGRO study will not change these risks. We do not anticipate that intravenous lidocaine will have any adverse effects in your overall recovery.
When taking any medicine there is always a very small risk of side-effects or allergies. Local anaesthetics such as lidocaine have been used every day in NHS hospitals and dentist practices for decades. Adverse reactions to lidocaine are rare but may include allergic reaction (including rash, swelling and blistering), dizziness, light-headedness, confusion, drowsiness, numbness of the mouth and/or tongue, blurred or double vision, breathlessness, hearing disorders (e.g. ringing in the ear), nausea and vomiting. The signs and symptoms of toxicity (overdose) are well known and treatable. If toxicity occurs during the infusion, you will be in the operating room or recovery room and under very close monitoring as part of normal care. There are no known late side-effects of lidocaine.

Where is the study run from?
Western General Hospital, Edinburgh, UK.

When is the study starting and how long is it expected to run for?
June 2017 to July 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
allegro@abdn.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Hugh Paterson

ORCID ID
https://orcid.org/0000-0003-4698-0131

Contact details
Western General Hospital
Colorectal Surgery Unit
Crewe Road
Edinburgh
United Kingdom
EH4 2XU
+44 (0)7780 957402
hugh.paterson@ed.ac.uk

Type(s)
Public

Contact name

Miss Allegro Team

Contact details
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
3rd Floor Health Sciences Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
-
allegro@abdn.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2017-003835-12

Protocol serial number
AC17067

Study information

Scientific Title
A placebo-controlled randomised trial of intravenous lidocaine in accelerating gastrointestinal recovery after colorectal surgery

Acronym
ALLEGRO

Study objectives
The primary aim is an effectiveness analysis to measure whether perioperative intravenous lidocaine achieves faster return of gut function for more patients after colorectal surgery. An initial internal pilot phase will be built into the trial to assess feasibility of recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service (WoSRES), 31/10/2017, 17/WS/0210

Study design
Multicentre double-blind parallel-group placebo-controlled randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colorectal resection for colorectal cancer or diverticular disease.

Interventions
Participants scheduled to undergo laparoscopic colectomy will be randomised on a 1:1 basis to either lidocaine or placebo. The participants will receive an intravenous bolus over 20 minutes of lidocaine hydrochloride 2% solution for injection at a dose of 1.5 mg/kg ideal body weight or placebo (0.9% sterile sodium chloride solution for injection) at induction of anaesthesia followed by intravenous infusion of lidocaine at1.5 mg/kg/hour ideal body weight with a maximum rate of 120 mg/hour or placebo for a minimum of 6 hours up to a maximum of 12 hours.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
lidocaine

Primary outcome(s)
Proportion of randomised subjects who have achieved return of gut function at 72 hours postoperatively. This will be measured by 'GI-3 recovery', a composite endpoint defined as achievement of both of the following two events: tolerating diet (defined as ingestion of food and drink without significant nausea or vomiting for 3 consecutive meals) and passage of flatus or stool (whichever comes first).

Key secondary outcome(s))
1. Time from start of operation to return of gut function using the GI-3 recovery definition (a composite endpoint defined as time from surgery to the later time to establish both of the following two events: tolerating diet without significant nausea or vomiting for 3 consecutive meals and first passage of flatus or stool) assessed using patient case report form (CRF) from medical notes
2. GI-2 recovery (defined as the time from start of operation to achieving both of the following two events: tolerating diet [defined as ingestion of food and drink without significant nausea or vomiting for 3 consecutive meals] and passage of stool) assessed using patient CRF from medical notes
3. Rate of prolonged postoperative ileus (PPOI), defined as failure to establish GI-3 by 120 hours after surgery (postoperative day 5) assessed using patient CRF from medical notes
4. Postoperative nausea and vomiting (PONV), including daily PONV score, number of episodes of vomiting (defined as episodes of expulsion of gastric content) and total dosage of rescue antiemetic in 72 hours after the start of the operation assessed using PONV questionnaire
5. Quality of analgesia using OBAS score daily in-hospital up to and including postoperative day 7
6. Total postoperative opioid consumption in morphine equivalent doses until 72 hours after start of operation, assessed using patient notes and recorded in CRF
7. Quality of recovery score assessed using a 15-question patient-reported outcome measure (PROM) questionnaire completed by patients daily while in hospital up to 7 days and at postoperative days 7 and 30
8. Quality of life assessed using EQ-5D questionnaire completed by patients daily while in hospital up to 7 days and at postoperative days 7, 30 and 90

9. Enhanced Recovery After Surgery protocol compliance measured by recording specific variables relevant to return of gut function from end of surgery until end of in-patient admission using medical records. The protocol items are:
9.1. Avoidance of long-acting opioids for maintaining anaesthesia
9.2. Prescribed PONV prophylaxis for 48 hours
9.3. Restrictive IV fluid policy aiming for euvolaemia, assessed by total IV fluid administration in 24 hours from start of anaesthesia and measuring patient weight pre- and 24 hours post operation.
9.4. Early feeding, with a carbohydrate supplement drink on day of surgery and solid food from postoperative day 1 onwards
9.5. Early mobilisation - patients should be out of bed for 2 hours on day of surgery and 4-6 hours every day thereafter AND walking
9.6. Routine postoperative laxative prescription
9.7. No nasogastric tube immediately after surgery
10. Time to achievement of medically-defined hospital discharge criteria (independent hydration /nutrition, adequate analgesia by oral route, independent mobilisation, return of gut function by GI-3 definition, no medical contraindication) recorded in patient CRF from patient medical notes
11. Time (days) to patient-reported readiness for discharge (must also have achieved medical criteria for discharge as noted above) assessed daily from day 2 onward using patient CRF from medical notes
12. Health economic evaluation with outcome measures determined through a model scoping exercise

Completion date
31/07/2023

Eligibility

Key inclusion criteria
Scheduled for elective colorectal resection for colorectal cancer or diverticular disease at participating UK colorectal surgery units. Right hemicolectomy, extended right hemicolectomy, left colectomy, sigmoid colectomy, subtotal colectomy with ileosigmoid or ileorectal anastomosis and high anterior resection are eligible.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
590

Key exclusion criteria

1. Planned epidural anaesthesia
2. Planned regional or local infiltration of lidocaine at the same time as lidocaine infusion
3. Pregnancy
4. Breastfeeding
5. Patients lacking capacity to give informed consent
6. Known or suspected allergy to lidocaine or amide-type local anaesthetics
7. Current complete heart block
8. Current severe liver dysfunction (Child's A or greater)
9. Current renal failure (eGFR <30)
10. Participation in the active intervention phase of another therapeutic clinical trial (or other interventional trial) unless a co-enrolment agreement is in place
11. Patients having surgery for indications other than colorectal cancer/diverticular disease
12. Rectal cancer below the peritoneal reflection in which total mesorectal excision is anticipated
13. Rectal cancer patients who have received any neoadjuvant radiotherapy
14. Preoperative surgical plan to form any new stoma during the primary procedure

Date of first enrolment
13/08/2018

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Western General Hospital NHS Lothian
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
ACCORD

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/11/2024	28/11/2024	Yes	No
Protocol article		28/01/2022	31/01/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2	13/10/2017	14/06/2018	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes