

Tranexamic acid to prevent anastomotic leak after rectal cancer surgery

Submission date 03/08/2024	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 31/10/2024	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 23/01/2026	Condition category Digestive System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Anastomotic leak is a life-threatening surgical complication that occurs when the two ends of bowel at the anastomosis fail to heal, causing spillage of bowel contents into the abdomen. Certain bacteria present within stool (the microbiome) have been shown to increase the risk of anastomotic leak by causing the join in the bowel to break down. This study will test a new treatment called tranexamic acid which may prevent this from happening.

This study aims to provide important information about tranexamic acid and whether it can be used to prevent anastomotic leak. Before this new treatment can be tested on a larger scale, it is important to do a small feasibility study to be sure the treatment is acceptable to patients and healthcare workers.

Who can participate?

Patients aged 18 years or older with a diagnosis of cancer of the rectum or sigmoid colon, suitable for curative resection by high or low anterior resection (open, laparoscopic, robotic).

What does the study involve?

Patients will be divided into two groups at random. One group will receive a solution of tranexamic acid into the back passage. This will be done using a small flexible tube (rectal catheter) which is placed into the anus during the operation. The catheter will remain in place for 3 days after surgery. This allows tranexamic acid to be delivered close to the join in the bowel, where it may modify bacteria that cause anastomotic leak. Participants allocated to the other group will receive sterile water through a rectal catheter without tranexamic acid. This will give an indication of whether tranexamic acid can influence bacteria at the anastomosis.

During the study, swabs will be used to take samples of bacteria from the back passage. This will be done before surgery, on the day of surgery, and after the final treatment. This is so that we can do further tests to see if the treatment is working against harmful bacteria. At the end of the study, we will invite patients/healthcare workers to talk to us about their experiences. This will help us to design a larger study to test if treatment with tranexamic acid works.

What are the possible benefits and risks of participating?

Benefits: It is hoped that this new treatment will help to prevent anastomotic leak after rectal cancer surgery. This is not certain and is the reason we are performing this study. Whilst this research may not directly benefit the participants, it will help us to better understand why anastomotic leak occurs and how we can improve treatments for this complication in the future.

Risks: Since participants are receiving an additional treatment, there is a risk of added side-effects, which means we must monitor them more closely.

All participants in this study will have a rectal catheter inserted during the operation by their surgeon. While this is a routine practice following surgery for some, it may cause slight discomfort.

Tranexamic acid is a widely used medication and most patients do not experience any adverse effects. However, all medicines carry potential side-effects. Some people taking tranexamic acid can develop nausea, vomiting or diarrhoea. Another possible side-effect is a rash. There are other less common side-effects which are possible with tranexamic acid, if participants notice anything unusual that they are concerned about, they must speak to a member of the medical team.

Where is the study run from?

University of Leeds (UK)

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

August 2024 to January 2027

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?

Jack Helliwell, J.A.Helliwell@leeds.ac.uk

Contact information

Type(s)

Scientific

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Additional identifiers

Integrated Research Application System (IRAS)

1009682

National Institute for Health and Care Research (NIHR)

303267

Protocol serial number

2022-CT01

Study information

Scientific Title

TrAnexamic acid to pRevent anastomotic leak after rectal cancer surGEry: a feasibility sTudy (TARGET)

Acronym

TARGET

Study objectives

Feasibility hypothesis 1: The administration of tranexamic acid via rectal catheter after rectal cancer surgery is feasible, acceptable, and safe.

Feasibility hypothesis 2: A definitive study of tranexamic acid for the prevention of anastomotic leak after rectal cancer surgery can be feasibly delivered in the future.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/10/2024, North West - Liverpool Central (2 Redman Place , Stratford, E20 1JQ, United Kingdom; +44 207 104 8340; liverpoolcentral.rec@hra.nhs.uk), ref: 24/NW/0254

Primary study design

Interventional

Study design

Phase II randomized controlled unblinded trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anastomotic leak; rectal cancer surgery

Interventions

Surgery will be performed according to the surgeon's usual technique. At the end of the procedure all participants will have a rectal catheter placed by the operating surgeon.

- Tranexamic Acid Group: Participants will receive tranexamic acid solution (1000mg/50ml) administered via a rectal catheter intra-operatively and on post-operative days 1-3.
- Control Group: Participants will receive sterile water (50ml) via rectal catheter intra-operatively and on post-operative days 1-3.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Tranexamic acid

Primary outcome(s)

Measured at the end of the study:

Outcomes to inform progression:

1. Number of eligible patients recruited.
2. Average compliance to the study treatment schedule.
3. Proportion of missing clinical outcome data.
4. Incidence of serious and unexpected serious complications.

Outcomes to explore clinical variability:

1. Anastomotic leak defined and graded using the International Study Group definition.
2. Post-operative complications measured using the Clavien-Dindo scale.

Key secondary outcome(s)

Exploratory outcomes for the two sub-studies:

Microbiome sub-study:

1. Bacterial 16S rRNA analysis to determine microbiome populations at the following time-points: i) pre-operative, ii) intra-operative, iii) on post-operative day 3-5.
2. Bacterial collagenase assay to quantify collagenase levels at the following time-points: i) pre-operative, ii) intra-operative, iii) on post-operative day 3-5.

Qualitative sub-study:

1. Patient and healthcare worker experiences of the intervention and the intervention schedule.
2. Enablers and barriers affecting compliance to the intervention.

Individual qualitative interviews will take place after treatment has been completed

Completion date

01/01/2027

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 23/01/2026:

1. Aged greater than or equal to 18 years
2. Able to provide written informed consent
3. Biopsy proven adenocarcinoma of the rectum or sigmoid colon or high-grade dysplasia with endoscopic/radiological evidence suggestive of cancer.
4. The responsible surgeon has determined the patient suitable for curative resection through either high or low anterior resection
5. The responsible surgeon has deemed the patient appropriate for elective open, laparoscopic or robotic surgery.
7. American Society of Anesthesiologists grade (ASA) less than or equal to 3
8. Able and willing to comply with the terms of the Protocol, including those related to pregnancy/ contraception

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5. The responsible surgeon has deemed the patient appropriate for elective open, laparoscopic or robotic surgery.
6. The responsible surgeon has deemed the planned level of distal bowel transection, and thus the level of the colorectal/anal anastomosis, to be ≤ 15 cm from the anal verge
7. American Society of Anesthesiologists grade (ASA) less than or equal to 3
8. Able and willing to comply with the terms of the Protocol, including those related to pregnancy/ contraception

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

Key exclusion criteria

Current key exclusion criteria as of 23/01/2026:

1. Patients not undergoing colo-rectal/anal anastomosis e.g., abdominoperineal excision of rectum (APER), Hartmann's procedure
2. Patients with coexistent colorectal pathology e.g., inflammatory bowel disease
3. Patients for whom the responsible surgeon considers there is a clear contraindication for tranexamic acid e.g. known allergy to tranexamic acid, a prior history of acute venous or arterial thrombosis, a medical history of seizures or convulsions, a medical history of disseminated intravascular coagulation, a medical history of severe renal impairment.
4. Patients who are breastfeeding, pregnant or likely to become pregnant within 3 months of surgery

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2. Patients with coexistent colorectal pathology e.g., inflammatory bowel disease
3. Patients for whom the responsible surgeon considers there is a clear contraindication for tranexamic acid e.g. known allergy to tranexamic acid, a prior history of acute venous or arterial thrombosis, a medical history of seizures or convulsions, a medical history of disseminated intravascular coagulation, a medical history of diseases of the retina, a medical history of severe renal impairment.
4. Patients who are breastfeeding, pregnant or likely to become pregnant within 3 months of surgery
5. Concurrent enrolment in another CTIMP
6. Concomitant administration of tranexamic acid for any other indication (tranexamic acid is not part of routine surgical care at LTHT)

Date of first enrolment

10/12/2024

Date of final enrolment

01/10/2026

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

St James's University Hospital

Leeds Teaching Hospitals NHS Trust

Beckett Street
Leeds
England
LS9 7TF

Sponsor information

Organisation

University of Leeds

ROR

<https://ror.org/024mrx33>

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

Results and Publications

Individual participant data (IPD) sharing plan

Data sharing requests will be considered by the trial management group on written request to the Chief Investigator. Fully anonymised participant data or other prespecified data will be available subject to a written proposal and signed data sharing agreement.

IPD sharing plan summary

Available on request