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IntAct- IFA to prevent anastomotic leak in rectal cancer surgery

Submission date	Recruitment status	[X] Prospectively registered
10/04/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/07/2025	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-to-reduce-a-serious-side-effect-of-rectal-cancer-surgery-intact

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34216

Study information

Scientific Title
IntAct: Intraoperative Fluorescence Angiography to Prevent Anastomotic Leak in Rectal Cancer Surgery

Acronym
IntAct

Study objectives
The aim of this study is to evaluate whether intraoperative fluorescent angiography (IFA) is able to decrease anastomotic leak (AL) rate in patients undergoing surgery for rectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 20/04/2017, ref: 17/NW/0193

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Imaging, Surgery

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Current interventions as of 19/02/2021:
880 participants will be randomised prior to surgery, on a 1:1 basis, to either surgery with IFA or surgery without IFA using minimisation (incorporating a random element) and stratified by surgeon, gender, ASA grade, T-stage, neo-adjuvant therapy, and tumour position.

Participants will receive an anterior resection either with or without IFA (intraoperative fluorescence angiography) depending on their randomised allocation:

Surgery with no IFA: The anterior resection (high or low) will be performed according to the surgeon's usual technique, using either a laparoscopic or robotic approach, with white light assessment of bowel perfusion. The specifics of each operation will be at the discretion of the operating surgeon.

Surgery with IFA: The anterior resection (high or low) will be performed according to the surgeon's usual technique, using either a laparoscopic or robotic approach. ICG (Indocyanine Green) will be administered intravenously at two points during the operation for perfusion assessment using near-infrared laparoscopy. A third dose of ICG will be permitted (e.g. extracorporeal assessment, or immediately prior to anastomosis) should the surgeon feel this to be beneficial. The specifics of each operation, including the decision to make a change to the planned anastomosis following IFA assessment, will be at the discretion of the operating surgeon.

All patients will be followed up until 90 days post-operation. Patients will be seen in clinic at 30 days and 90 days post operation, and a rectal contrast enema scan will be performed at 4-6 weeks post operation. Patients will complete quality of life and health resource use questionnaires at baseline, 30 and 90 days post operation. There is an additional 12 month follow-up for UK patients for whom the 12 month post-operative time point falls before the end of the planned follow-up period i.e. 90 days following the last participant's operation; patients will complete quality of life and health resource use questionnaires at this time point but will not need to be seen in clinic at this time as the clinical trial follow-up data will be collected from their medical notes.
For patients in the microbiome sub-study (UK patients only), faecal samples will be taken at baseline, intra-op, and at 3-5 days post operatively.

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For patients in the microbiome sub-study (200 UK patients), faecal samples will be taken at baseline, intra-op and at 3-5 days post operatively. For patients in the perfusion sub-study, two additional scans will be performed pre-operatively (CT angiography and CT perfusion).

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical anastomotic leak rate is defined as per the International Study Group of Rectal Cancer definition, as a confirmed defect of the intestinal wall at the anastomotic site (including suture and staple lines of neorectal reservoirs) leading to a communication between the intra- and extraluminal compartments that has an impact on patient management, as assessed through clinical examination within 90 days post operation

Secondary outcome measures
Current secondary outcome measures as of 19/02/2021:
1. Change in planned anastomosis during surgery, including the decision to undertake a permanent stoma rather than an anastomosis, the site of proximal bowel used for anastomosis, the site of rectal remnant used for anastomosis, and the decision to undertake a diverting stoma
2. Rate of defunctioning stoma (temp or permanent)
3. Operative and post-operative complications (Clavien-Dindo for complication-level classification and Comprehensive Complication Indicator for patient-level classification) within 90 days of operation
4. Length of post-operative hospital stay
5. Low Anterior Resection Syndrome (LARS) score at 30 days and at 90 days post-operation in patients without defunctioning ileostomy
6. Rate of re-interventions within 90 days
7. Quality of life is assessed using the QLQ-C30, QLQ-CR29, and EQ-5D at 30 days and 90 days post-operation
8. Health resource utilisation assessed at 30 days and 90 days post-operation
9. Death within 90 days of operation

Mechanistic sub-study:
1. Changes in rectal microbiome and correlation to anastomotic leak

Previous secondary outcome measures:
1. Change in planned anastomosis during surgery, including the decision to undertake a permanent stoma rather than an anastomosis, the site of proximal bowel used for anastomosis, the site of rectal remnant used for anastomosis, and the decision to undertake a diverting stoma
2. Rate of defunctioning stoma (temp or permanent)
3. Operative and post-operative complications (Clavien-Dindo for complication-level classification and Comprehensive Complication Indicator for patient-level classification) within 90 days of operation
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6. Rate of re-interventions within 90 days
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8. Health resource utilisation assessed at 30 days and 90 days post-operation
9. Death within 90 days of operation

Mechanistic sub-study
1. Presence of vascular variants, presence of atherosclerosis within IMA
2. Presence of stenosis (≤or >50%) in the internal iliac artery, internal pudendal artery, superior rectal, middle rectal or inferior rectal artery
12. Difference in regional blood flow, blood volume or permeability surface area product in patient with or without anastomotic leak, no and prior (chemo)radiation, and intra-operative fluorescence
13. Changes in rectal microbiome and correlation to anastomotic leak

Overall study start date
01/09/2016

Completion date
14/02/2024

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Able to provide written informed consent.
3. Diagnosis of rectal cancer (defined as a lower margin up to 15cm from the anal verge as assessed by endoscopic or radiological assessment)
4. Suitable for curative resection by high or low anterior resection
5. Suitable for elective laparoscopic or robotic surgery
6. ASA less than or equal to 3
7. Able and willing to comply with the terms of the protocol including QoL questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 880; UK Sample Size: 440

Key exclusion criteria

Current participant exclusion criteria as of 19/02/2021:
1. Patients not undergoing colo-rectal/anal anastomosis e.g. abdominoperineal excision of rectum (APER), Hartmann's procedure
2. Patients undergoing synchronous colonic resections
3. Locally advanced rectal cancer requiring extended or multi-visceral excision
4. Recurrent rectal cancer
5. Coexistent colorectal pathology e.g. synchronous cancers, inflammatory bowel disease
6. Previous pelvic radiotherapy for pathology unrelated to diagnosis with rectal cancer e.g. treatment for prostate cancer
7. Hepatic dysfunction, defined as Model for End-Stage Liver Disease (MELD) Score > 10
8. Renal dysfunction, defined as eGFR < 40mmol/l
9. Known allergy to ICG, iodine, iodine dyes, or taking drugs known to interact with ICG e.g. anticonvulsants, bisulphite containing drugs, methadone, nitrofuratoin
10. Pregnant or likely to become pregnant within 3 months of surgery
11. Immunocompromised patients e.g. taking steroids or receiving immunotherapy

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6. Previous pelvic radiotherapy for pathology unrelated to diagnosis with rectal cancer e.g. treatment for prostate cancer
7. Hepatic dysfunction, defined as Model for End-Stage Liver Disease (MELD) Score > 10
8. Renal dysfunction, defined as eGFR < 40mmol/l
9. Known allergy to ICG, iodine, iodine dyes, or drugs known to interact with ICG e.g. anticonvulsants, bisulphite containing drugs, methadone, nitrofuratoin
10. Use of oral antibiotics within 8 weeks prior to randomisation
11. Pregnant or likely to become pregnant within 3 months of surgery

Date of first enrolment
01/07/2017

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
Belgium

England

Germany

Ireland

Italy

Netherlands

Slovenia

United Kingdom

Study participating centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

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University of Leeds

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

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

Publication and dissemination plan
Current publication and dissemination plan as of 19/02/2021:
Planned publication in a high-impact peer-reviewed journal approximately in 2023.

Previous publication and dissemination plan:
Planned publication in a high-impact peer-reviewed journal approximately in 2022.

Intention to publish date
31/03/2025

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Plain English results	version 1.0	26/02/2025	26/02/2025	No	Yes
Results article		18/07/2025	22/07/2025	Yes	No