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A feasibility study of electron radiotherapy delivered during a surgical operation for rectal cancer

Submission date 13/05/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/05/2022	**Overall study status** Completed	
Last Edited 10/06/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Rectal cancer is a cancer that occurs in the pelvis from the rectum. Locally advanced rectal cancer outgrows the rectum and attaches to other body parts in the pelvis and locally recurrent rectal cancer is a rectal cancer that comes back after surgery, and usually attaches to many different pelvic structures. They are both difficult to manage. The standard of care treatment involves chemotherapy and radiotherapy, followed by what is known as an extended margin operation to remove all cancer affected organs and not leave any cancer cells behind. If cancer cells reach the edge of the removed tissue, there is a high chance of leaving cancer cells behind. This is a key predicter of negative outcome in patients. Intraoperative electron beam radiotherapy (IOERT) was developed to help improve patient outcomes. Once the cancer has been removed, the surgeon and a cancer radiotherapy specialist examine the patient's scans, the cancer specimen and the area the cancer was in, and if there is concern about small numbers of cancer cells being left behind they treat the area with radiotherapy to destroy these cells.

Who can participate?

Patients aged 16 years or older, that are due to receive treatment for the above subsets of rectal cancer will be approached to take part.

What does the study involve?

If eligible on the day of surgery the patient will be randomised to one of three arms: Arm A – standard of care (No IOERT), Arm B – extended margin surgery plus IOERT (10 Gy), or Arm C – extended margin surgery plus higher dose IOERT (15 Gy). The surgeon, cancer specialist team and patient will be blinded to study treatment. Patients will be followed up at 30 days, 3 months and for a minimum of 12 months post surgery as part of the trial and they will be followed up for 5 years as part of standard care.

What are the possible benefits and risks of participating?

The information that we get from this study may help us to treat future patients with the same condition in a more effective way. You will also be helping to further our knowledge of how to treat cancer and this will also benefit society as a whole.

As with every treatment plan, there are associated risks. The risk from surgery includes bleeding, wound infections and a rare chance of death which can occur in less than 1% of people who require surgery. However, all patients will have consented to surgery which is the standard of care. The associated risk from the intraoperative radiotherapy is low and includes wound infections, pain from pelvic nerves, and a narrowing of the tube which carries urine from the kidney to the bladder. The risks of IOERT are counterbalanced however by the potential benefits of better cancer treatment and less chance of cancer recurrence and thereby potential survival.

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?
April 2021 to April 2025

Who is funding the study?
IntraOp Medical Corporation (USA)
PLANETS cancer charity (UK)

Who is the main contact?
Daniel Griffiths, Dpg1e20@soton.ac.uk

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
292873

Central Portfolio Management System (CPMS)
52098

Study information

Scientific Title
A double-blinded feasibility study of intraoperative electron radiotherapy in patients with locally advanced or locally recurrent rectal cancer

Acronym
ELECTRA

Study objectives
To determine acceptability and feasibility of recruiting, randomising and delivering IOERT in a randomised controlled trial (RCT) setting as preparatory work for a future late phase RCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/03/2022, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0048

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

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

Interventions
As part of standard of care, patients with locally advanced or locally recurrent rectal cancer will have an extended margin operation to remove all cancer affected organs.

Participants who meet the eligibility criteria and whom provide their written informed consent for the study will be randomised to one of three study arms: Arm A - extended margin surgery alone (standard of care treatment), Arm B - extended margin surgery with IOERT standard dose (10 Gy), Arm C - extended margin surgery plus IOERT higher dose (15 Gy). Participants will have equal chances to receive one of the three arms of treatment. Randomisation will occur on the day of surgery and the surgeon, cancer specialist team and the patient will be blinded to the result of the randomisation.
The IOERT session will take place in a purposefully designed operating theatre with a portable self-shielded electron beam linear accelerator, known as the MOBETRON. The treating radiation oncologist will determine how the IOERT will be administered based on best practice.
The tests included in the study are a cardiopulmonary exercise test and MRI scans, which are standard of care. A pregnancy test will also be conducted for women of childbearing potential at screening and pre-op, which is not standard of care.
The patients will be asked to complete quality of life and health economics questionnaires at their baseline visit and at 3 and 12 months post surgery.
Participants will be followed up for a minimum of a year in the trial and at the end of the trial they will return to standard care to be followed up until 5 years post surgery. The participants will be followed up at 30 days, 3, 12 and 24 months post surgery as part of the trial.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Feasibility measured at the end of the trial using:
1. Number and percentage of patients meeting eligibility criteria and number of patients referred to a specialist MDT over the trial period;
2. Number and percentage of patients accepting randomisation;
3. Number and percentage of patients for which IOERT was successfully delivered as planned;
4. Number and percentage of patients and clinicians for which blinding was maintained for IOERT delivery;
5. Percentage of patients whose questionnaires can be analysed;
6. Percentage of patients whom we can collect information on potential primary outcomes;

Key secondary outcome(s)
1. Morbidity measured using Clavien Dindo at surgery and at 30 days post randomisation
2. Mortality at 30 days post randomisation
3. Oncological outcomes: IOERT field occurrence, overall recurrence, overall survival at minimum 12 months post randomisation
4. Treatment related toxicity graded by CTCAE at minimum 12 months post randomisation
5. Time to local or systemic recurrence
6. R1 rate at surgery
7. Quality of life measured using questionnaires (EQ-5D-5L, LRRC-QoL, SF-36, EORTC QLQ-C30) at pre-op, 3 months and 12 months post surgery
8. Resource use and cost at pre-op, 3 months and 12 months post surgery

Completion date
25/04/2025

Eligibility

Key inclusion criteria

1. Age >=16 years
2. Non-metastatic/oligo-metastatic (up to three lesions from 2 sites predicted to be radically treatable) – locally advanced or locally recurrent disease involving the posterior or lateral compartment of the pelvis and predicted to be resectable but with close margins from MRI as determined by a specialist MDT (sMDT)
3. Specialist colorectal MDT review with experience in pelvic exenteration, which
4. has proposed IOERT as an option for treatment
5. Patient suitable for IOERT as a component of treatment in view of the
6. responsible Clinical Oncologist
7. Performance status <=1 as defined by the Eastern Cooperative Group (ECOG)
8. Deemed medically fit for surgery
9. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
31

Key exclusion criteria
Current participant exclusion criteria as of 11/08/2023:
1. Unresectable disease/likelihood of R2 resection
2. sMDT determined excess prior radiotherapy within IOERT target zone
3. Women who are pregnant or breastfeeding
4. Participation within an interventional trial within 3 months of the point of registration within ELECTRA

Previous participant exclusion criteria:
1. Unresectable disease/likelihood of R2 resection
2. sMDT determined excess prior radiotherapy within IOERT target zone
3. Women who are pregnant or breastfeeding
4. Use of experimental drugs within other interventional clinical trials

Date of first enrolment
20/05/2022

Date of final enrolment
25/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
University of Southampton and University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
England
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Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
IntraOp Medical Corporation

Funder Name
PLANETS cancer charity

Results and Publications

Individual participant data (IPD) sharing plan

Individual participant data will be made available, including data dictionaries, for approved data sharing requests. Individual participant data will be shared that underlie the results after deidentification and normalisation of information (text, tables, figures, and appendices). The study protocol and statistical analysis plan will also be available. Anonymous data will be available for request from 3 months after the publication of the results to researchers who provide a completed data sharing request form that describes a methodologically sound proposal, for the purpose of the approved proposal and if appropriate, signed a data-sharing agreement. Pseudonymised participant data within the clinical trial dataset will be available for sharing via controlled access by authorised Southampton Clinical Trials Unit (SCTU) staff. The request for data access will need to detail the specific requirements and the proposed research, statistical analysis, publication plan and evidence of research group qualifications. Data access requests will be reviewed against specific eligibility criteria by the SCTU data custodian and key members of the trial team. Data will be shared once all parties have signed relevant data sharing documentation covering SCTU conditions for sharing and if required, an additional data sharing agreement from the sponsor. Proposals should be directed to ctu@soton.ac.uk.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications	Novel approaches adopted in the design, development, and implementation	21/01/2025	10/06/2026	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes