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A study of functional and immunological outcomes in people undergoing robotic and non-robotic rectal cancer surgery

Submission date
12/05/2022

Recruitment status
No longer recruiting

Registration date
08/08/2022

Overall study status
Completed

Last Edited
08/08/2022

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is an observational, prospective, single-centre study comparing 2 surgical techniques used to treat rectal cancer patients. The investigated techniques will be the standard keyhole technique (also called laparoscopic or minimal invasive (MIS) surgery) and the robot-assisted technique. Robot-assisted surgery uses the robotic systems to aid the surgical procedures, providing more precision, flexibility, and control than is possible with standard keyhole technique. Our hypothesis is that this may also result in less harm to surrounding tissues.

Our main interests will be to compare the stress response after surgery and the restoration of digestive, urinary and sexual functions after surgery. We are looking to recruit 80 patients within 2 years with a follow-up period of 12 months.

Who can participate?
Adults over 18 years, diagnosed with rectal cancer

What does the study involve?
To compare the surgical stress response between the groups, we will be taking blood samples before surgery and on the first, third and fifth day after surgery (with the day of surgery being day 0). We will assess the functional outcomes through validated questionnaires filled in before surgery, and at 6 and 12 months after surgery.
The research team will also gather further information about the recovery and cancer treatment by reviewing the patient's medical records during follow-up.

What are the possible benefits and risks of participating?
This study will not affect the surgical after care of patients in both groups. After completing this study, we hope to have a better insight into which technique causes less harm to the surrounding structures by observing the stress response and functional outcomes after rectal cancer surgery. The ambition of this work is to increase knowledge on surgical techniques for rectal cancer management, and to improve standard of care for these patients.

Where is the study run from?
Portsmouth Hospitals University NHS Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to February 2025

Who is funding the study?
1. BASO ~ The Association for Cancer Surgery (UK)
2. Intuitive Foundation (USA)

Who is the main contact?
Prof Jim Khan jim.khan@porthosp.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310837

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52049, IRAS 310837

Study information

Scientific Title
A prospective cohort study of Functional and Immunological outcomes after Laparoscopic and Robotic Total Meso-rectal Excision for rectal cancer

Acronym
FILTER

Study objectives
Does robotic rectal cancer surgery result in a more precise dissection with a reduced immune /stress response and does it lead to better functional outcomes as compared to laparoscopic surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2022, South Central - Hampshire B Research Ethics Committee (Health Research Authority, Skipton House, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 207 104 8089; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0051

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Colorectal surgery for colorectal cancer

Interventions
The total study duration will be approximately 3 years. Study follow-up will be 12 months after date of surgery. Patients will have their blood drawn before surgery, and on days 1, 3 and 5 after surgery (with the date of surgery being day 0).
Patients will be asked to fill in questionnaires on functional outcomes before surgery and at 6 and 12 months after surgery.

The Baseline visit
After informed consent is obtained, pre-operative baseline information will be collected. At this moment in time the participant will be asked to complete the pre-operative questionnaires on

urinary function, sexual function, digestive function and the baseline quality of life questionnaires. A baseline bloodsample will be drawn. Patients have a standard of care preoperative clinical visit, where anorectal manometry measurements will be done if possible.

The Operative Procedure visit
During the operation routinely recorded parameters will be collected. These include how long the operation takes, system and instrument use, conversion to an open surgery and any complications during the surgery.

The Post-Operative Course
Following surgery, patients will be admitted to a ward as per standard clinical care. Patients will receive standard postoperative care as per clinical pathways, with all treatment decisions made as per clinician expertise. Study blood samples will be collected on days 1, 3 and 5 (with the date of surgery being day 0). Routinely patients are expected to be discharged on day 5, but if a patient is discharged home earlier than this there will be no need for additional blood sampling after discharged. For the purpose of calibration, we may need to draw extra blood for the first 10 patients. All study bloods are to be processed as per lab manual and routine blood tests (WBC, CRP, NRL, etc.) will be processed as per local procedure.

Follow-up visits
30 days
Around 30 days postoperatively, the patient's records will be checked to assess postoperative complications, readmissions, patient related outcomes, surgical outcomes, and adverse events.

6 months
At 6 months postoperatively, the patient will receive the questionnaire surveys to fill out (digitally or by mail) and will be contacted by the research team (digitally or by phone) for follow-up and to answer any questions regarding the study.

12 months
At 12 months postoperatively, the patient will attend a standard care follow-up visit with the clinical team, who will perform an anorectal manometry if possible. They will receive the questionnaire surveys to fill out (digitally, by mail or in person) and will be contacted by the research team (digitally, by phone or in person) for follow-up and to answer any questions regarding the study.

The trial does not require any additional investigation or patient contact throughout its duration.

Intervention Type
Procedure/Surgery

Primary outcome measure
To assess the stress response after rectal cancer surgery and the assessment of sexual, urological and bowel function after rectal cancer surgery.This will be based on 2 primary outcome measurements.
1. Measurement of the stress response by taking blood samples at baseline and on postoperative days 1, 3 and 5:
1.1. White cell count
1.2. CRP
1.3. NLR (neutrophil lymphocyte ratio)
1.4. IL-6
1.5. IL-10

1.6. TNFa
1.7. MPO (neutrophil myeloperoxidase)
2. Functional assessment of sexual, urological and bowel function with the use of validated questionnaires at 12 months:
2.1. International Prostatic Symptoms Score (IPSS) (male)
2.2. International Index of Erectile Function (IIEF) (male)
2.3. Female Sexual Function Index (FSFI) (female)
2.4. Kings Health Questionnaire (KH) (female)
2.5. LARS-score (male/female)
2.6. Vaizey score (male/female)

Secondary outcome measures
1. Quality of life assessment using validated questionnaires (EORTC QLQ-C30/ CR29 and EQ-5D) at baseline, after 6 months and after 12 months.
2. Surgical outcomes, such as operative time, blood loss, stoma application, conversion, and intra-operative complications
3. Patient-related outcomes at 12 months measured using patient records:
3.1. Length of hospital stay
3.2. Opioid requirements and compliance with ERP
3.3. Worst vital signs post op
3.4. Worst pain scores
3.5. Time to flatus (in days) and return of bowel function
3.6. Early morbidity (up to 30-day postoperative complications, Clavien-Dindo Classification)
3.7. Early mortality
3.8. Adverse events.
4. Optional: assessment of anorectal physiology after laparoscopic or robotic surgery in rectal cancer patients by using an anorectal manometry at baseline and after 1 year(Assessment will be done in the outpatient clinic when patients come for their standard care preoperative and 12-month follow-up visit. The manometry will be performed by the clinical team using departmental equipment.)

Overall study start date
22/10/2021

Completion date
01/02/2025

Eligibility

Key inclusion criteria
1. Age 18 years or above.
2. Diagnosed with rectal cancer, up to 15cm from the anal verge.
3. Local MDT recommends rectal cancer surgery (i.e. (high) anterior resection, partial TME, complete TME)
4. Patient assessed as fit for surgery (ASA I-III).
5. Patient willing and able to give informed consent for participation in the study.
6. Elective surgery.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Key exclusion criteria
1. Patient planned for Abdominoperineal Excision of Rectum (APER) or Hartmann's procedure
2. Patients with confirmed or suspected metastatic disease.
3. Pregnant or breastfeeding patients.
4. Previous pelvic radiation for other cancers.
5. Inflammatory bowel disease (IBD).
6. Other known auto-immune disease which might influence the immune response (such as advanced liver disease, human immunodeficiency virus infection, Hepatitis B or C virus).
7. Use of anti-inflammatory medication (i.e. corticosteroids, anti-inflammatory drugs, immune modulating drugs, chronic use of antibiotics (the use of NSAIDS and steroid asthma inhalers will not be considered an exclusion criteria).
8. High pre-operative C-reactive protein (CRP) levels (>20).

Date of first enrolment
20/04/2022

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals University National Health Service Trust
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Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Research organisation

Funder Name
BASO ~ The Association for Cancer Surgery

Alternative Name(s)
BASO~Association of Cancer Surgery, BASO~ACS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name

Intuitive Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/02/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Participant information sheet	version 2.4	06/05/2022	27/06/2022	No	Yes
Protocol file	version 4.1	16/06/2022	27/06/2022	No	No
HRA research summary			26/07/2023	No	No