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Comparing international data between keyhole and robotic rectal cancer surgery

Submission date 26/10/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/12/2023	**Overall study status** Completed	
Last Edited 14/04/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
This study is an investigation into the medical outcomes of patients with rectal cancer who underwent a surgical procedure called "Total Mesorectal Excision" (TME) with the assistance of robotic technology. Instead of studying patients in real-time, we're taking a look back in time to analyse data from multiple medical centers where this robotic surgical technique was used.
The primary goal of our research is to determine whether the use of robots in TME surgery has a positive impact on the long-term health and recovery of patients with rectal cancer. We aim to collect and analyse data, comparing the outcomes of patients who had robot-assisted TME surgery with those who underwent traditional procedures.

Who can participate?
Patients aged 18 years or older who underwent rectal cancer surgery beginning in 2014.

What does the study involve?
We aim to combine retrospective data from 3 European datasets (for an estimated total of 3,000 inclusions) to perform high-quality statistical analyses on surgical outcomes (such as length of stay, operative time, and conversion) between laparoscopic and robotic proctectomy with partial or complete TME surgery. We will only be collecting data on patients treated after 2014 in all centres. The study will also have secondary objectives, such as complications, reinterventions and readmissions, pathological outcomes, stoma formation and reversal, and short- and long-term oncological outcomes (local recurrence, distant recurrence, disease-free survival, and overall survival).

What are the possible benefits and risks of participating?
None

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

When is the study starting and how long is it expected to run for?
June 2023 to June 2025

Who is funding the study?
Intuitive Foundation (USA)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319973

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56922, IRAS 319973

Study information

Scientific Title
Retrospective, Propensity Score Matched Analysis of Short- and Long-term Outcomes in Laparoscopic versus Robotic Total Mesorectal Excision: an international, multi-centre data study

Acronym
RESOLUTION

Study objectives

Current study hypothesis as of 05/02/2025:

This study is a retrospective, multi-centre data study analysing the oncological outcomes in rectal cancer patients that underwent robotic "Total Mesorectal Excision" (TME) surgery. We aim to combine retrospective data from 3 European datasets (for an estimated total of 3,000 inclusions) to perform high quality statistical analyses on surgical outcomes (such as length of stay, operative time, and conversion) between laparoscopic and robotic proctectomy.

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Previous study hypothesis:

This study is a retrospective, multi-centre data study analysing the oncological outcomes in rectal cancer patients that underwent robotic "Total Mesorectal Excision" (TME) surgery. We aim to combine retrospective data from 3 European datasets (for an estimated total of 3,000 inclusions) to perform high quality statistical analyses on surgical outcomes (such as length of stay, operative time, and conversion) between laparoscopic and robotic proctectomy with partial or complete TME surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/06/2023, HRA and Health and Care Research Wales (HCRW) (5-15, Castlebridge, 19 Cowbridge Rd E, Cardiff, CF11 9AB, United Kingdom; +44 (0)2920 230457; healthandcareresearch@wales.nhs.uk), ref: 23/HRA/2175

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
Current interventions as of 05/02/2025:

This is a multicentre, retrospective cohort study for comparative analysis of postoperative surgical outcomes and short- and long-term oncological outcomes after rectal cancer surgery using propensity score-matched cohorts.

The study is looking to include all eligible patients treated after 2014 whose data is available at one of the three participating sites and estimates an inclusion of 3000 patients in total. All data transfer will comply with local and UK privacy laws, and have been outlined in a "Data Sharing Agreement" and "Data Management Plan". After reception at the Sponsor site, data will be checked for errors and converted to a file suitable for statistical analysis. This process has been outlined in detail in the "Data Management Plan" as well.

This study will not have any influence on the care or lives of patients included in the study. There is no direct benefit and no additional risk for included patients. A patient is eligible for inclusion when they meet all the inclusion criteria and none of the exclusion criteria for the study, as outlined in the protocol.

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Previous interventions:

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Intervention Type
Procedure/Surgery

Primary outcome measure
The primary outcome variables will be measured using data held in pre-existing databases at each of the participating sites from rectal cancer patients who underwent robotic total mesorectal excision (TME) surgery at one timepoint:
1. Length of stay in days after surgery
2. Operative time in minutes
3. Blood loss in millilitres

Secondary outcome measures
The secondary outcome variables will be measured using data held in pre-existing databases at each of the participating sites from rectal cancer patients who underwent robotic total mesorectal excision (TME) surgery at one timepoint:
1. Intraoperative and postoperative complications recorded as timepoint, type of complication,

and Clavien-Dindo classification grading of complication
2. Reinterventions and readmissions after surgery recorded as yes/no and timepoint
3. Pathological outcomes recorded as the number of positive lymph nodes, differentiation grading, quality of the specimen, and positivity of circumferential resection margins
4. Stoma formation as yes/no and type, as well as reversal of stoma and timepoint of reversal
5. Local recurrence of disease as yes/no and timepoint
6. Distant recurrence of disease as yes/no, timepoint, and location of recurrence
7. Disease-free survival as yes/no and timepoint
8. Overall survival as yes/no and timepoint

Overall study start date
01/06/2023

Completion date
01/06/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/02/2025:

1. All patients who underwent a laparoscopic or robotic proctectomy since 2014;
2. Aged 18 years or above;
3. Rectal cancer tumour located within 15 cm from the anal verge or 20 cm from the anorectal junction.

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Previous inclusion criteria:

1. All patients who underwent a laparoscopic or robotic proctectomy with partial or complete TME after 2015;
2. Aged 18 years or above;
3. Rectal cancer tumour located within 15 cm from the anal verge or 20 cm from the anorectal junction.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 3,000; UK Sample Size: 900

Key exclusion criteria
Current exclusion criteria as of 05/02/2025:

1. Patients that underwent robotic TME surgery as part of a more complex procedure, for example a peritonectomy, or a synchronous colonic or hepatic resection.
2. Patients that underwent palliative resection
3. Patients that underwent emergency resection

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Previous exclusion criteria:

1. Patients that underwent an APER or Hartmann's procedure
2. Patients that underwent robotic TME surgery as part of a more complex procedure, for example a peritonectomy, or a synchronous colonic or hepatic resection.
3. Patients that underwent palliative resection
4. Patients that underwent emergency resection

Date of first enrolment
04/07/2023

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
England

France

Netherlands

United Kingdom

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre

Centre Hospitalier Universitaire de Lyon
Lyon
France
-

Study participating centre
University Medical Centre Groningen
Groningen
Netherlands
-

Study participating centre
Montpellier Cancer Institute
Montpellier
France
-

Study participating centre
Bordeaux Colorectal Institute
Bordeaux
France
-

Study participating centre
Amsterdam Medical Centre
Amsterdam
Netherlands
-

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

Sponsor details
Southwick Hill Road
Portsmouth
England
United Kingdom

PO6 3LY
+44 (0)2392286000
research.office@porthosp.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Charity

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 and peer-reviewed

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/04/2025	14/04/2025	Yes	No