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Robotic versus laparoscopic resection for rectal cancer

Submission date 27/04/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/05/2010	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-robotic-assisted-keyhole-surgery-for-cancer-of-the-rectum

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01736072

Protocol serial number
EME 08/52/01

Study information

Scientific Title
RObotic versus LAparoscopic Resection for Rectal cancer: an international, multicentre, prospective, randomised, controlled, unblinded, parallel-group trial of robotic assisted versus laparoscopic surgery for the curative treatment of rectal cancer

Acronym
ROLARR

Study objectives
The current proposal aims to test the hypothesis that robotic-assistance facilitates laparoscopic rectal cancer surgery. On short-term follow-up this should result in a reduction in the conversion rate and no worsening of the circumferential resection margin (CRM) positivity rate. On longer-term follow-up, the increased accuracy should improve post-operative bladder and sexual function, enhance quality of life (QoL), and ensure there is no increase in local disease recurrence.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/eme/085201/#/

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds West Research Ethics Committee, version 2.0 approved provisionally on 19/03/2010, ref: 10/H1307/27
Version 3.0 approved 24/08/2010
v4.0 01/03/2011 approved 22/03/2011

Study design
International multicentre prospective randomised controlled unblinded parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rectal cancer, laparoscopic and robotic assisted laparoscopic surgery

Interventions
A total of 400 patients (200 in each arm) will be recruited into the trial over an 18-month period. It is anticipated that approximately 15 patients per month will be recruited in the first 6 months, with monthly recruitment increasing to approximately 25 patients in the final 12 months. Patients will be randomised on a 1:1 basis to receive either robotic-assisted or standard laparoscopic rectal cancer surgery and will be allocated a unique trial number. Laparoscopic mesorectal resection will be performed in accordance with each surgeons usual practice. Robotic-assisted laparoscopic surgery may involve either a totally robotic or a hybrid approach; the only absolute requirement being that the robot is used for mesorectal resection. For the purposes of ROLARR, a totally robotic and a hybrid operation are defined as follows:
1. A totally robotic operation involves a resection of the entire surgical specimen with the use of

robotic-assistance.
2. A hybrid operation involves the use of laparoscopic techniques to mobilise the proximal colon with robotic-assistance employed to perform the rectal mesorectal dissection.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Rate of conversion to open surgery as an indicator of surgical technical difficulty.
Conversion is defined as the use of a laparotomy wound for any part of the mesorectal dissection. The use of a limited laparotomy wound to facilitate a low stapled anastomosis and/or specimen extraction is permissible and not defined as an open conversion.

Key secondary outcome(s))
Current information as of 15/09/2010:
1. Accuracy of surgery (oncological efficacy)
1.1. Pathological CRM positivity rates as recorded from local histopathology review, where resection margin positivity is defined as a distance of ≤1mm of the cancer from any resection margin.
1.2. 3-year local recurrence rates as calculated from the cumulative incidence function plot of time to local recurrence, where time to local recurrence is defined as the time from date of randomisation to date of local recurrence. Local recurrence is defined as evidence of locoregional disease within the surgical field.
2. Intra-operative and post-operative (30 day and 6 month) complications and 30-day operative mortality. Thirty-day operative mortality is defined as deaths occurring from any cause during the first 30 post-operative days
3. Patient self-reported bladder and sexual function as assessed by the International Prostate Symptom Score (IPSS) for male and female bladder function, and the International Index of Erectile Function (IIEF) and Female Sexual Function Index (FSFI) for sexual function
4. Patient self-reported generic health related QoL as assessed by the SF-36 v2.0 and fatigue assessed by the Multidimensional Fatigue Inventory (MFI-20)
5. Three-year disease-free and overall survival. Overall survival is defined as the time from date of randomisation to date of death from any cause. Disease-free survival is defined according to Punt et als definitions as the time from date of randomisation to date of death from any cause, recurrent disease (locoregional or distant recurrence) or second primary cancer (the date of recurrence/secondary cancer is defined as the date of the relevant (e.g. clinical or radiological) assessment which detects the recurrence/secondary cancer).
6. Health economics:
6.1. Preference based QoL measured by EQ-5D and used to calculate quality-adjusted life-years (QALYs)
6.2. Direct resource utilisation
6.3. Cost-effectiveness estimated using QoL and direct resource use information combined with apportioned cost scenarios of the robotic device
6.4. Intra-operative laparoscopic skills (randomly selected cases only) as assessed by an independent expert blind to surgeon and surgery performed using the global assessment tool for evaluation of intra-operative laparoscopic skills 'GOALS'
6.5. Quality of the plane of surgery as assessed by local histopathology review as detailed in Appendix 1 of the protocol

Initial information at time of registration:
1. Accuracy of surgery (oncological efficacy)
1.1. Pathological CRM positivity rates as recorded from local histopathology review, where resection margin positivity is defined as a distance of ≤1mm of the cancer from any resection margin.
1.2. 3-year local recurrence rates as calculated from the cumulative incidence function plot of time to local recurrence, where time to local recurrence is defined as the time from date of randomisation to date of local recurrence. Local recurrence is defined as evidence of locoregional disease within the surgical field.
2. Intra-operative and post-operative (30 day and 6 month) complications and 30-day operative mortality. Thirty-day operative mortality is defined as deaths occurring from any cause during the first 30 post-operative days
3. Patient self-reported bladder and sexual function as assessed by the International Prostate Symptom Score (IPSS) for male and female bladder function, and the International Index of Erectile Function (IIEF) and Female Sexual Function Index (FSFI) for sexual function
4. Patient self-reported generic health related QoL as assessed by the SF-36 v2.0 and fatigue assessed by the Multidimensional Fatigue Inventory (MFI-20)
5. Three-year disease-free and overall survival. Overall survival is defined as the time from date of randomisation to date of death from any cause. Disease-free survival is defined according to Punt et als definitions as the time from date of randomisation to date of death from any cause, recurrent disease (locoregional or distant recurrence) or second primary cancer 5.
6. Health economics:
6.1. Preference based QoL measured by EQ-5D and used to calculate quality-adjusted life-years (QALYs)
6.2. Direct resource utilisation
6.3. Cost-effectiveness estimated using QoL and direct resource use information combined with apportioned cost scenarios of the robotic device
6.4. Intra-operative laparoscopic skills (randomly selected cases only) as assessed by an independent expert blind to surgeon and surgery performed using the global assessment tool for evaluation of intra-operative laparoscopic skills 'GOALS'
6.5. Quality of the plane of surgery as assessed by central review of photographs, blind to surgeon and surgery performed

Completion date
30/09/2014

Eligibility

Key inclusion criteria
Current information as of 15/09/2010:
1. Aged greater than or equal to 18 years
2. Able to provide written informed consent
3. Diagnosis of rectal cancer* amenable to curative surgery either by low anterior resection, high anterior resection, or abdominoperineal resection i.e. staged T1-3, N0-2, M0 by imaging as per local practice; although not mandated, CT imaging with either additional MRI or transrectal ultrasound is recommended to assess distant and local disease.
(*For the purposes of the ROLARR trial, rectal cancer is defined as an adenocarcinoma whose distal extent is situated at or within 15cm of the anal margin as assessed by endoscopic examination or radiological contrast study)
4. Rectal cancer suitable for resection by either standard or robotic-assisted laparoscopic procedure

5. Fit for robotic-assisted or standard laparoscopic rectal resection
6. American Society of Anestheologists (ASA) physical status classification less than or equal to 3
7. Capable of completing required questionnaires at time of consent

Initial information at time of registration:
1. Aged greater than or equal to 18 years
2. Able to provide written informed consent
3. Diagnosis of rectal cancer amenable to curative surgery either by anterior resection or abdominoperineal resection (i.e. staged T1-3, N0-2, M0 by Computed Tomography [CT] and Magnetic Resonance Imaging [MRI] or transrectal ultrasound)
4. Rectal cancer suitable for resection by either standard or robotic-assisted laparoscopic procedure
5. Fit for robotic-assisted or standard laparoscopic rectal resection
6. American Society of Anestheologists (ASA) physical status classification less than or equal to P3
7. Capable of completing required questionnaires at time of consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
466

Key exclusion criteria
Current information as of 15/09/2010:
1. Benign lesions of the rectum
2. Benign or malignant diseases of the anal canal
3. Locally advanced cancers not amenable to curative surgery
4. Locally advanced cancers requiring en bloc multi-visceral resection
5. Synchronous colorectal tumours requiring multi-segment surgical resection (n.b. a benign lesion within the resection field in addition to the main cancer would not exclude a patient)
6. Co-existent inflammatory bowel disease
7. Clinical or radiological evidence of metastatic spread
8. Concurrent or previous diagnosis of invasive cancer within 5 years that could confuse diagnosis (non-melanomatous skin cancer or superficial bladder cancer treated with curative intent are acceptable. For other cases please discuss with Chief Investigator via Clinical Trials Research Unit [CTRU])
9. History of psychiatric or addictive disorder or other medical condition that, in the opinion of the investigator, would preclude the patient from meeting the trial requirements

10. Pregnancy (a pregnancy test is not mandated for the purpose of this trial)
11. Participation in another rectal cancer clinical trial relating to surgical technique

Initial information at time of registration
1. Benign lesions of the rectum
2. Cancers of the anal canal
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9. History of psychiatric or addictive disorder or other medical condition that, in the opinion of the investigator, would preclude the patient from meeting the trial requirements
10. Pregnancy
11. Participation in another rectal cancer clinical trial relating to surgical technique

Date of first enrolment
01/06/2010

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
United Kingdom

England

Australia

Denmark

Finland

France

Germany

Italy

Korea, South

Singapore

United States of America

Study participating centre
University of Leeds
Leeds
United Kingdom
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Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Efficacy and Mechanism Evaluation Programme (ref: EME 08/52/01)

Alternative Name(s)
NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/06/2018		Yes	No
Results article	sub study results	01/02/2020	26/02/2020	Yes	No
Protocol article	protocol	01/02/2012		Yes	No
Plain English results			26/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes