

Robotic versus laparoscopic resection for rectal cancer

Submission date 27/04/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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>

Study website

http://medhealth.leeds.ac.uk/info/430/solid_tumours/1645/rolarr

Contact information

Type(s)

Scientific

Contact name

Mr David Jayne

Contact details

CTRU
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)113 343 1477
rolarr@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01736072

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a patient information sheet

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 surgeon's 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 measure

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.

Secondary outcome measures

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 ≤ 1 mm 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 al's 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 ≤ 1 mm 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 al's 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

Overall study start date

01/06/2010

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 Anesthesiologists (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 Anesthesiologists (ASA) physical status classification less than or equal to P3
7. Capable of completing required questionnaires at time of consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

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
3. Locally advanced cancers not amenable to curative surgery
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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**

Australia

Denmark

England

Finland

France

Germany

Italy

Korea, South

Singapore

United Kingdom

United States of America

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9JT

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

c/o Rachel de Souza

Faculty Research Ethics and Governance Administrator

Faculty of Medicine and Health Research Office

Room 10.110, Level 10, Worsley Building

Clarendon Way

Leeds

England

United Kingdom

LS2 9NL

+44 (0)113 343 2274

governance-ethics@leeds.ac.uk

Sponsor type

University/education

Website

<http://www.leeds.ac.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, 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, EME

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

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