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The role of 3D laparoscopic rectal surgery: a randomised controlled trial

Submission date 09/12/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/12/2015	**Overall study status** Completed	
Last Edited 10/01/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-improve-keyhole-surgery-for-rectal-cancer

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
2D vs. 3D laparoscopic anterior resection: a randomised controlled trial

Study objectives
Using 3D imaging reduces intra-operative technical errors enacted during laparoscopic anterior resection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Berkshire B Research Ethics Committee, 24/02/2016, ref: 16/SC/0118

Study design
Multicentre randomized controlled 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 participant information sheet

Health condition(s) or problem(s) studied
Rectal adenocarcinoma

Interventions
Patients will be identified at local colorectal Multi-Disciplinary Team meetings and outpatient clinics. Potentially eligible patients will be approached by GCP (Good Clinical Practice) trained staff with delegated responsibility at each centre, who will discuss the study with the patient

and answer any questions. Patients will be given a written site specific participant information sheet to take away. If willing and eligibility is confirmed, written consent will be obtained and the patient randomised. All trial participating centres and trial surgeons are experienced in using 3D imaging systems.

Centralised randomisation will take place at Yeovil Hospital Clinical Research Unit. Allocation into one of two groups will be determined using pre-prepared computerised random number generation (zero or one) to allocate in a 1:1 ratio:

1. Group 1 patients undergo laparoscopic anterior resection using a 2D imaging system.
2. Group 2 patients undergo laparoscopic anterior resection using a 3D imaging system.

Intervention Type
Device

Primary outcome measure
The total number of technical errors during each operation. Each operation will be digitally recorded and analysed unedited by a blinded assessor using Objective Clinical Human Reliability Analysis (OCHRA)

Secondary outcome measures
1. Total operating time
2. Operative blood loss
3. Conversion to open surgery
4. Postoperative length of stay
5. 30 day readmission
6. Histological outcomes, including mesorectal specimen quality, which will be assessed by a pathologist using standardised criteria
7. Postoperative complications using the Clavien-Dindo classification
8. 30 day mortality
9. Surgeon-reported feedback on the adverse effects of the imaging system will also be recorded such as blurred vision, altered vision, light headedness and or dizziness
10. Surgeon-reported cognitive load assessment

All complications occurring in hospital (index stay or re-admission) will be recorded up to 30 days.

Overall study start date
01/01/2015

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Patients diagnosed with adenocarcinoma of the rectum (<15cm from anal verge as measured by staging MRI)
2. Scheduled to undergo elective laparoscopic TME/ partial mesorectal excision surgery with curative intent, with or without neo-adjuvant treatment and with or without defunctioning stoma formation
3. Written informed patient consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
72

Total final enrolment
88

Key exclusion criteria
1. History of inflammatory bowel disease
2. Patients requiring abdomino-perineal excision or surgery without anastomosis
3. Advanced tumours involving adjacent organs (TNM5 T4aNxMx)
4. Surgery performed with palliative intent or under unplanned/emergency settings
5. Previous treatment (radiotherapy/abdominopelvic surgery) for endometrial, ovarian, prostate, bladder (TURBT ok), anal or vaginal cancer
6. Patient or surgeon refusal to enter study or accept randomisation result

Date of first enrolment
02/01/2016

Date of final enrolment
30/03/2018

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Frimley Park Hospital
Portsmouth Road
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GU16 7UJ

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

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

Sponsor information

Organisation
Yeovil District Hospital NHS Foundation Trust

Sponsor details
Higher Kingston
Yeovil
England
United Kingdom
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Sponsor type
Hospital/treatment centre

Website
www.yeovil.nhs.uk

ROR
https://ror.org/00v5nyn36

Funder(s)

Funder type
Industry

Funder Name
European Association of Endoscopic Surgeons

Funder Name
Karl Storz GmbH & Co

Results and Publications

Publication and dissemination plan
The findings will be written up for publication in Surgical Endoscopy as per contract with the funding body (European Association of Endoscopic Surgery) and will be presented at EAES congress meeting in May 2018 and ACPGBI conference in July 2018. The outcome of this project would be described during educational events organised by the Clinical Research Unit, Yeovil.

Intention to publish date
01/01/2019

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

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?
Results article	results	01/10/2019	13/03/2019	Yes	No
Plain English results			24/03/2021	No	Yes
Results article	Factors predicting operative difficulty	01/12/2019	10/01/2023	Yes	No

HRA research summary	28/06/2023	No	No