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

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

#### 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

**Contact name** Mr Nader Francis

#### **Contact details** Yeovil District Hospital Yeovil United Kingdom BA21 4AT

**Type(s)** Scientific

Contact name

Mr Nathan Curtis

#### **Contact details**

Yeovil District Hospital Yeovil United Kingdom BA21 4AT

# 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 Frimley United Kingdom 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 BA21 4AT 01935 475122 joanna.allison@ydh.nhs.uk **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 create	d Date added Peer reviewed	? Patient-facing?
<u>Results article</u>	results	01/10/2019	13/03/2019 Yes	No
<u>Plain English results</u>			24/03/2021 No	Yes
<u>Results article</u>	Factors predicting operative difficult	<sup>y</sup> 01/12/2019	10/01/2023 Yes	No

HRA research summary

No