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The “R-3D-2” pilot study - the impact of rehearsal strategies prior rectal cancer surgery, using patient individualised 3D models

Submission date 14/06/2015	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/07/2015	**Overall study status** Completed	
Last Edited 21/03/2017	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-improve-surgery-for-rectal-cancer-r-3d-2-study

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
165586

Study information

Scientific Title
The “R-3D-2” pilot study - randomised controlled trial on the impact of surgical rehearsal strategies in rectal cancer surgery using 3d models by using 2 methods

Acronym
The “R-3D-2” pilot study

Study objectives
The aim of this study is to test the feasibility of recruitment of patients and surgeons who are ready to perform structured mental rehearsal using virtual and physical rehearsal aids for minimally invasive anterior resection/total mesorectal excision for rectal cancer.

Hypothesis 1: Using patient specific virtual models to mentally rehearsal a procedure will improve surgical performance and reduce patient complications after keyhole rectal cancer surgery
Hypothesis 2: Using patient specific physical (plastic) models for rehearsal procedures will improve surgical performance and reduce patient complications even further compared to mental rehearsal with virtual models only

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Leeds East, 15/03/2015, ref: 15/YH/0134

Primary study design
Interventional

Study design
Interventional multi-centre randomized controlled trial

Study type(s)
Other

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

Interventions
Surgeons operating on patients randomised to group 1 will undergo Structured Mental Rehearsal (SMR) using patient specific 3D Virtual models.
Surgeons operating on patients randomised to group 2 will do the same, as well as practice on a patient specific “physical” (plastic) model.
Surgeons operating on patients randomised to group 3 will undergo Structured Mental Rehearsal using Magnetic resonance (MR) scans.
Added 20/03/2017: Surgeons operating on group 4 will undergo their routine preparation, without additional intervention.

The SMR process is based on a standardisation of the anterior resection technique, the outcome of a consensus of international experts.

Preparation of 3D virtual models: These models will be prepared through a process called 3D reconstruction. Routine MR images of patients are “uploaded” onto a 3D segmentation /reconstruction software. Through a semi-automatic process pelvic organs (rectum, mesorectum, vagina/prostate and seminal vesicles, bladder and ureters), pelvic skeleton and tumour will be “reconstructed” in a three dimensional form.

Preparation of “physical” (plastic) models: The dissection plane (mesorectal envelope) will be printed into a physical model using 3D printing technology. This will act as the mould of the outline of the dissection plane, which will be placed into a generic (non patient-specific) pelvic cavity. The surgeon will be asked to dissect this outline off the generic pelvic cavity model using laparoscopic instruments.

Intervention Type
Other

Primary outcome(s)
Surgical performance assessed by video assessment methods (Competency Assessment Tool and Objective Clinical Human Reliability Assessment (OCHRA)). Surgical performance will be assessed for each real procedure. This will be done by recording the pelvic dissection at the time of surgery through the laparoscopic camera. The recording will be sent to two experts who will rate it independently using two validated scoring systems. This process will be repeated for each procedure.

Key secondary outcome(s)
1. Peri-operation complications and time to complete surgery will be recorded at the time of surgery
2. Post-operative complications will be recorded after surgery until the patient is discharged from hospital. The patients will not be followed up after they leave the hospital.
3. Specimen quality (margins of dissected tissue clear/not clear of cancerous cells, number of lymph nodes retrieved). This will be recorded for each patient, once this information becomes available from our pathology laboratory.
4. Transcripts of SMR sessions. Each SMR session will be audio recorded and transcribed for qualitative analysis. This will be done throughout the data collection part of the study.
5. Semi-structured interviews. Conducting these interviews aims to explore the overall opinion of surgeons about the SMR process and the patient specific models. These will be conducted after the end of the data collection process.

Completion date
22/05/2017

Eligibility

Key inclusion criteria
1. Patients due to undergo minimally invasive surgery for rectal cancer surgery
2. They have to be older than 18 years of age
3. Both genders
4. All operations must be performed or supervised by surgeons who performed similar operations > 50 times in the past

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 20/03/2017:
1. Patients planned for a primary Hartmann's resection (no anastomosis planned)
2. Patients planned for abdominoperineal resection (APR)
3. Patients with anal cancer and benign lesions
4. Patients who cannot represent their interests and lack the capacity to consent for themselves

Previous exclusion criteria:
1. Patients planned for a primary Hartmann's resection (no anastomosis planned)
2. Patients planned for abdominoperineal resection (APR)
3. Patients planned for primary open surgery, partial mesorectal excision (PME)
4. Patients planned for transrectal surgery, "bottom up" surgery
5. Patients with anal cancer and benign lesions
6. Patients who cannot represent their interests and lack the capacity to consent for themselves

Date of first enrolment
22/05/2015

Date of final enrolment
22/05/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
St James University Hospital
Leeds, West Yorkshire
United Kingdom
-

Study participating centre
Pinderfields General Hospital
Wakefield, West Yorkshire
United Kingdom
-

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals Charitable Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised data will be kept at the University of Leeds secure server for 3 years after the completion of the study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No