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Surgical timing after radiotherapy for rectal cancer

Submission date 24/05/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/05/2012	**Overall study status** Completed	
Last Edited 15/08/2016	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-surgery-following-treatment-rectal-cancer-starrcat

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
12185

Study information

Scientific Title

STARRCAT: Surgical Timing After Radiotherapy for Rectal Cancer Analysis of Technique: a pilot randomised controlled trial

Acronym
STARRCAT

Study objectives
In patients with low rectal cancer receiving neo-adjuvant long-course chemoradiotherapy performing surgical resection at 12 weeks as opposed to 6 weeks after completion of the neoadjuvant therapy result in a less complex surgical procedure and improved outcomes?

Methodology:
A pilot randomised controlled trial. Surgery for low rectal cancer will be performed after a delay of either 6 or 12 weeks - the timing allocated by randomisation. Operations will be video-recorded, and the videos analysed using human reliability assessment techniques to evaluate the complexity of the procedure and the effect that this has upon the completeness of the surgical resection. Data will also be collected on peri-operative morbidity and mortality, quality of life, and patient experience.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS South West REC Exeter, 16/05/2012, ref: 12/SW/0112

Primary study design
Interventional

Study design
Randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network, Generic Health Relevance and Cross Cutting Themes; Subtopic: Colorectal Cancer, Rectum, Surgery

Interventions
12 weeks: surgery for rectal cancer performed following 12-week delay from completion of neo-adjuvant long-course chemoradiotherapy

6 weeks: surgery for rectal cancer performed following 6-week delay from completion of neo-adjuvant long-course chemoradiotherapy.

Follow Up Length: 1 month(s)

Intervention Type
Mixed

Primary outcome(s)
Operative Technical Complexity measured at time of surgical intervention

Key secondary outcome(s)
1. Down-staging of disease as assessed on magnetic resonance imaging (MRI) measured at 6 weeks following completion of neo-adjuvant therapy +/- at 12 weeks
2. In-hospital surgical complications measured at time of discharge & also at 30-days post-operatively
3. Length of hospital inpatient admission measured by counting day of surgery as day 0 until day of discharge
4. Mortality measured 30 days from operation
5. Oncological clearance of tumour ("R0 resection") - Histopathological analysis of surgical resection specimen
6. Quality of life: EORTC QLQ-CR29 & C30 and EQ-5D-5L questionnaires measured pre-operatively
7. Post-operative on day of discharge from hospital measured 2-weeks after discharge in clinic
8. Quality of resected specimen assessed from high-definition photography of resected tumour specimens
9. Rates of sphincter preservation measured following surgery
10. Re-admission rates measured 30-days following operation
11. Surgeon-Reported Operative Complexity measured at using questionnaire completed by the operating surgeon at the end of each procedure
12. Tumour response to chemoradiotherapy measured using operative resection specimen assessed using standard histopathological techniques

Completion date
11/10/2014

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Completing neo-adjuvant long-course
3. Chemoradiotherapy for rectal cancer
4. Fit for surgical resection by open or laparoscopic anterior resection or abdominoperineal excision (APE)
5. American Society of Anaesthesiology (ASA) grades I, II and III
6. Able and willing to provide written consent
7. Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Key exclusion criteria
1. Emergency admission or bowel obstruction/perforation
2. Short course radiotherapy regime
3. Anal cancer
4. Metastatic disease
5. Previous palliative pelvic radiotherapy
6. Rectal cancer on top of inflammatory bowel disease
7. Contra-indication to Magnetic Resonance Imaging scanning
8. Poor cognitive ability and/or unable to provide consent
9. Pregnancy

Date of first enrolment
06/06/2012

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Yeovil District Hospital (UK)

ROR
https://ror.org/05dvbq272

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2016		Yes	No