

# Surgical timing after radiotherapy for rectal cancer

<b>Submission date</b> 24/05/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/08/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Study design

Randomised interventional treatment 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 the contact details below to request a patient information sheet

## 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 measure**

Operative Technical Complexity measured at time of surgical intervention

## **Secondary outcome measures**

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

## **Overall study start date**

06/06/2012

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 50; UK Sample Size: 50

**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**

England

United Kingdom

**Study participating centre**

**Yeovil District Hospital**

Yeovil

United Kingdom

BA21 4AT

# Sponsor information

## Organisation

Yeovil District Hospital (UK)

## Sponsor details

Higher Kingston

Yeovil

England

United Kingdom

BA21 4AT

## Sponsor type

Hospital/treatment centre

## Website

<http://www.yeovilhospital.nhs.uk/>

## ROR

<https://ror.org/05dvbq272>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Research for Patient Benefit Programme (UK)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Results article</a>	results	01/10/2016		Yes	No