

# A multicentre randomised phase II clinical trial comparing oxaliplatin (Eloxatin), capecitabine (Xeloda) and pre-operative radiotherapy with or without cetuximab followed by total mesorectal excision for the treatment of patients with magnetic resonance imaging defined high risk rectal cancer

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/10/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/06/2014	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

Protocol serial number

## Study information

### Scientific Title

### Acronym

EXPERT-C

### Study objectives

To evaluate the improvement in pathological complete response rate from the addition of cetuximab to neoadjuvant oxaliplatin and capecitabine followed by synchronous chemoradiation and Total Mesorectal Excision (TME) in patients with Magnetic Resonance Imaging (MRI) defined high risk rectal cancer.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Oxfordshire Research Ethics Committee A, approval was given on 05/04/2005

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Rectal cancer

### Interventions

Group one: receiving oxaliplatin (Eloxatin), capecitabine (Xeloda) and pre-operative radiotherapy with cetuximab followed by TME.

Group two: receiving oxaliplatin (Eloxatin), capecitabine (Xeloda) and pre-operative radiotherapy without cetuximab followed by TME.

### Intervention Type

Drug

### Phase

Phase II

### Drug/device/biological/vaccine name(s)

Oxaliplatin, capecitabine, cetuximab.

### Primary outcome(s)

Pathological complete response at TME.

### **Key secondary outcome(s)**

1. Radiological response rates after neoadjuvant chemotherapy and after completion of all neoadjuvant chemoradiotherapy
2. Complete resection rate (R0 resection) with microscopic clear resection margin (tumour observed more than 1 mm from the resection margin), especially circumferential resection margin
3. Perioperative measures including operation time, duration of in-patient stay, peri-operative transfusion requirement and mortality within 30 days of operation
4. Post-operative complications including wound infection, wound dehiscence fistula formation
5. Quality of TME as graded by audit of photographed surgical specimens
6. Rate of Abdomino-Peritoneal Excision (APE)
7. Rate of permanent defunctioning colostomies
8. Clinical and radiological anastomotic leak rate
9. Progression free survival and patterns of failure
10. Overall survival
11. Safety
13. Quality of life including long term bowel function
13. Evaluation of molecular and genetic predictors of response to anti-Epidermal Growth Factor Receptor (anti-EGFR) treatment
14. Evaluation of gene expression changes which occur in response to treatment with cetuximab, and to correlate these changes with response to treatment and prognosis.

### **Completion date**

01/09/2012

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years or over
2. Histological diagnosis of adeno- or undifferentiated non-small cell carcinoma of rectum
3. High risk operable rectal cancer as defined by the presence on MRI of at least one of the following:
  - a. tumours within 1 mm of mesorectal fascia i.e. circumferential resection margin threatened or involved
  - b. T3 tumours at/below levators
  - c. tumours extending into more than or equal to 5 mm into peri-rectal fat
  - d. T4 tumours (including the involvement of bladder or vagina if surgical resection is possible with clear margins)
  - e. presence of extra-mural venous invasion (primary tumour is therefore at least T3)
4. World Health Organisation (WHO) performance status of zero to two
5. No evidence of metastatic disease as determined by Computerised Tomography (CT) scan of chest and abdomen or other investigations such as Positron Emission Tomography (PET) scan or biopsy if required
6. Adequate bone marrow function with platelets more than  $100 \times 10^9/l$ , White Blood Cells (WBC) more than  $3 \times 10^9/l$  and neutrophils more than  $1.5 \times 10^9/l$
7. Serum bilirubin less than  $1.5 \times$  Upper Limit of institutional Normal range (ULN) and transaminases less than  $2.5 \times$  ULN
8. Serum creatinine less than ULN or calculated creatinine clearance more than 50 ml/min
9. No concurrent uncontrolled medical condition

10. No active malignant disease other than non-melanotic skin cancer or carcinoma in situ of the uterine cervix in the last ten years
11. Life expectancy of more than three months
12. Adequate contraceptive precautions if relevant
13. Informed written consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Any contraindications to MRI (e.g. patients with pacemakers)
2. Medical or psychiatric conditions that compromise the patients ability to give informed consent
3. Patients with rectal cancer which is deemed inoperable at diagnosis should not be entered into the study even if they are potentially operable if their primary is successfully downstaged by neoadjuvant treatment. This includes patients with locally advanced inoperable disease, such as tumour extending beyond the mesorectal fascia into pelvic side wall structures, or situations where surgical resection with clear margins is unlikely to be possible
4. T1-2 rectal cancer at any level
5. Presence of metastatic disease or recurrent rectal tumour
6. Concurrent uncontrolled medical conditions
7. Any previous chemotherapy or radiotherapy, and any investigational treatment for rectal cancer
8. Pregnancy or breast feeding
9. Patients with known malabsorption syndromes or a lack of physical integrity of the upper gastrointestinal tract
10. Clinically significant (i.e. active) cardiac disease (e.g. congestive heart failure, symptomatic coronary artery disease and cardiac dysrhythmia, e.g. atrial fibrillation, even if controlled with medication) or myocardial infarction within the last 12 months
11. Patients with any symptoms or history of peripheral neuropathy

**Date of first enrolment**

01/09/2005

**Date of final enrolment**

01/09/2012

**Locations**

## Countries of recruitment

United Kingdom

England

## Study participating centre

Royal Marsden Hospital

Surrey

United Kingdom

SM2 5PT

## Sponsor information

### Organisation

Royal Marsden NHS Foundation Trust (UK)

### ROR

<https://ror.org/0008wzh48>

## Funder(s)

### Funder type

Industry

### Funder Name

Professor Cunningham's Clinical Research Fund, Merck Pharmaceuticals (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?
<a href="#">Results article</a>	results	01/12/2013		Yes	No
<a href="#">Results article</a>	results	23/06/2014		Yes	No

<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
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