

# Chemotherapy or no chemotherapy in clear margins after neoadjuvant chemoradiation in locally advanced rectal cancer. A randomised phase III trial of control vs capecitabine plus oxaliplatin.

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
16/10/2003	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
11/11/2003	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
25/10/2022	Cancer	

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-or-no-chemotherapy-after-surgery-for-rectal-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

Clinical Trials Information System (CTIS)  
2004-001484-21

**ClinicalTrials.gov (NCT)**

NCT00427713

**Protocol serial number**

CHRONICLE

## Study information

**Scientific Title**

Chemotherapy or no chemotherapy in clear margins after neoadjuvant chemoradiation in locally advanced rectal cancer. A randomised phase III trial of control vs capecitabine plus oxaliplatin.

**Acronym**

CHRONICLE

**Study objectives**

Locally advanced rectal cancer is difficult to manage. Pre-operative chemoradiotherapy is used increasingly in the UK to downstage and treat the disease. The value of further postoperative chemotherapy is a matter of widespread debate. The role of 5-FU in this setting is being addressed in other studies. The aim of this trial is to determine whether a non-cross resistant chemotherapy will achieve a better outcome for patients. This trial also provides a unique opportunity to collect pathological specimens before and after chemoradiation for analysis of predictors of response and resistance to 5-FU based chemoradiation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Locally advanced rectal cancer

**Interventions**

Randomisation between:

Interventions:

Arm A: Control, standard follow-up

Arm B: six cycles at three weekly intervals (18 weeks):

a. Capecitabine 1000mg/m<sup>2</sup> on day one to day 14, twice daily

b. Oxaliplatin 130 mg/m<sup>2</sup> on day one by 120 minute intravenous infusion

**Assessments:**

Six, 12, 18, 24 and 36 months - abdomino-pelvic Computed Tomography (CT) scan or UltraSound (US) and chest x-ray or thoracic CT

**Follow-up:**

Three monthly for two years, six monthly next three years then annually

**Intervention Type**

Drug

**Phase**

Phase III

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

Capecitabine, oxaliplatin

**Primary outcome(s)**

Three year disease free survival of 85% power to detect a 10% increase i.e. 40% to 50%.

**Key secondary outcome(s)**

1. Overall survival
2. Toxicity

**Completion date**

01/12/2007

## Eligibility

**Key inclusion criteria**

1. Patients aged 18 and over
2. Histologically proven locally advanced rectal carcinoma
3. Pre-operative fluoropyrimidine based chemoradiation, minimum dose 45 Gy
4. Complete resection of primary tumour with clear margins
5. Able to start treatment within 12 weeks of surgery
6. Normal Full Blood Counts (FBCs), Urea and Electrolytes (U+Es) and Liver Function Tests (LFTs)
7. Creatinine clearance more than or equal to 50 ml/min
8. World Health Organisation performance status less than two
9. Patient consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

113

**Key exclusion criteria**

1. Unsuitable for chemotherapy:
  - a. known DPD deficiency
  - b. hypersensitivity to platinum
  - c. not recovered from surgery
  - d. peripheral neuropathy
  - e. moderate or severe renal impairment
  - f. malabsorption syndrome
2. Prior oxaliplatin, irinotecan and mitomycin
3. Taking warfarin or antiviral agents
4. Previous malignancies or serious uncontrolled medical conditions

**Date of first enrolment**

01/11/2004

**Date of final enrolment**

01/12/2007

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Mount Vernon Centre for Cancer Treatment**

Northwood

United Kingdom

HA6 2RN

## Sponsor information

**Organisation**

University College London (UK)

**ROR**

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research UK (ref: C10568/A4148)

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2007		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>		25/10/2022		No	Yes