

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.

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

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/m² on day one to day 14, twice daily

b. Oxaliplatin 130 mg/m² 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

https://ror.org/02jx3x895

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?
Results article	results	01/06/2007		Yes	No
Plain English results			25/10/2022	No	Yes