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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	[X] Prospectively registered [_] Protocol
Registration date 11/11/2003	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 25/10/2022	**Condition category** Cancer	[_] 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

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Additional identifiers

EudraCT/CTIS number
2004-001484-21

IRAS number

ClinicalTrials.gov number
NCT00427713

Secondary identifying numbers
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 chemoradiotherapyis 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 aimof 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 chemoradiationfor 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

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
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^2 on day one to day 14, twice daily
b. Oxaliplatin 130 mg/m^2 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 measure
Three year disease free survival of 85% power to detect a 10% increase i.e. 40% to 50%.

Secondary outcome measures
1. Overall survival
2. Toxicity

Overall study start date
01/11/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

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. malabsorbtion syndrome
2. Prior oxaliplatin, irinotecan and mitomycin
3. Taking warfarinor 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
England

United Kingdom

Study participating centre
Mount Vernon Centre for Cancer Treatment
Northwood
United Kingdom
HA6 2RN

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
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WC1E 6BT

Sponsor type
University/education

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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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