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EXCITE: Erbitux, Xeloda, Campto, Irradiation Then Excision for locally advanced rectal cancer

Submission date 23/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 23/04/2010	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 01/10/2026	**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-cetuximab-capecitabine-and-irinotecan-with-radiotherapy-before-surgery-for-cancer-of-the-rectum

Contact information

Type(s)
Scientific

Contact name
Miss Emma Williams

Contact details
Cancer Trials Office
90 Tottenham Court Road
London
United Kingdom
W1T 4TJ

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00972881

Clinical Trials Information System (CTIS)
2007-006701-25

Protocol serial number
4265

Study information

Scientific Title
EXCITE: Erbitux, Xeloda, Campto, Irradiation Then Excision for locally advanced rectal cancer (North West/North Wales Clinical Oncology Group-04 on behalf of the NCRI rectal cancer subgroup): a phase II trial from the North West/North Wales Clinical Oncology Group on behalf of the NCRI rectal cancer subgroup examining the toxicity and efficacy of Cetuximab, Capecitabine and Irinotecan in combination with radiotherapy as preoperative downstaging treatment for MRI-defined locally advanced rectal cancer

Acronym
EXCITE

Study objectives
To assess the downstaging effectiveness and tolerability of preoperative chemoradiation therapy (CRT) using capecitabine/irinortecan/cetuximab plus radiotherapy.

Treatment summary:
Patients will be treated with pelvic radiotherapy to a planned volume at a dose of 45 Gy in 25 daily fractions of 1.8 Gy treating 5 days per week from Monday to Friday for five weeks in total. Concurrently they will receive oral capecitabine at 650 mg/m^2 twice daily (bd) for 5 days per week on the days of radiotherapy only. In addition, they will receive intravenous (IV) irinotecan at 60 mg/m^2 once per week during the 1st, 2nd, 3rd and 4th weeks of radiotherapy. In addition to this they will receive a loading dose of IV cetuximab at 400 mg/m^2 one week before the commencement of radiotherapy and then at 250 mg/m^2 once per week during the 1st, 2nd, 3rd 4th and 5th weeks of radiotherapy.

On 20/10/2010 the following changes were made to this trial record:
1. The anticipated end date was changed from 30/03/2010 to 30/08/2011.
2. The phase was changed from phase I/II to phase II only.
3. The target number of participants was changed from 40 to 80.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee REC B, 15/01/2008, ref: 08/H0605/6

Primary study design
Interventional

Study design
Randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Colorectal Cancer; Disease: Rectum

Interventions
Patients will be treated with pelvic radiotherapy to a planned volume at a dose of 45 Gy in 25 daily fractions of 1.8 Gy treating 5 days per week from Monday to Friday for five weeks in total.

Concurrently they will receive oral capecitabine at 650 mg/m^2 bd for 5 days per week on the days of radiotherapy only. In addition, they will receive IV irinotecan at 60 mg/m^2 once per week during the 1st, 2nd, 3rd and 4th weeks of radiotherapy. In addition to this they will receive a loading dose of IV cetuximab at 400 mg/m^2 one week before the commencement of radiotherapy and then at 250 mg/m^2 once per week during the 1st, 2nd, 3rd 4th and 5th weeks of radiotherapy.

Follow-up length: 36 months
Study entry: registration only

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Capecitabine, irinortecan, cetuximab

Primary outcome(s)
Histologically confirmed R0 resection rate, measured at surgery when the tumour is resected (captured on Surgery CRF)

Key secondary outcome(s)
1. Radiotherapy compliance, measured during treatment weeks
2. Grade 3 or 4 toxicity, measured from treatment week 1 until end of follow-up month 36
3. Pathological complete response, measured at surgery when tumour is resected and examined
4. Morbidity, measured from surgery until end of follow-up month 36
5. Disease-free survival and local failure-free survival, measured from end of treatment until end of follow-up month 36

Completion date
30/08/2011

Eligibility

Key inclusion criteria
Amended as of 20/10/2010:
1. Rectal cancer staged with magnetic resonance imaging (MRI) as locally advanced:
1.1. Mesorectal fascia threatened (tumour less than or equal to 1 mm from mesorectal fascia)
1.2. Mesorectal fascia involved or breached
1.3. Low tumours arising less than 5 cm from the anal verge
2. Histologically confirmed adenocarcinoma with lower (distal) limit less than or equal to 12 cm from the anal verge using rigid sigmoidoscopy
3. No evidence of metastatic disease
4. No pre-existing condition which would deter radiotherapy, e.g. fistulas, severe ulcerative colitis, Crohn's disease, prior adhesions
5. Estimated glomerular filtration rate (GFR) greater than 50 ml/min. If this is less than 50 ml/min a 24-hour urine collection for estimation of GFR is required or a serum EDTA clearance.
6. Absolute neutrophil count greater than or equal to 1.5 x 10^9/l
7. Platelets greater than or equal to 100 x 10^9/l, serum bilirubin less than 1.25 x upper limit of

normal (ULN), serum transaminase less than 3 x ULN, serum ALP less than 5 x ULN
8. Fit to receive all study treatments
9. Able to comply with oral medication
10. Easter Cooperative Oncology Group (ECOG) performance status 0 or 1
11. Informed consent
12. Male and female, aged over 18 years

Initial information at time of registration:
1. Magentic resonance imaging (MRI) defined locally advanced rectal cancer:
1.1. Mesorectal fascia involved, or
1.2. Mesorectal fascia threatened (tumour <1 mm from mesorectal fascia), or
1.3. Any T3 tumours less than 5 cm from anal verge
2. Histologically confirmed adenocarcinoma
3. No evidence of metastatic disease
4. No pre-existing condition which would deter radiotherapy, e.g. fistulas, severe ulcerative colitis, Crohn's disease, prior adhesions
5. Estimated glomerular filtration rate (GFR) greater than 50 ml/min. If this is less than 50 ml/min a 24-hour urine collection for estimation of GFR is required or a serum EDTA clearance.
6. Absolute neutrophil count greater than or equal to 1.5 x 10^9/l
7. Platelets greater than or equal to 100 x 10^9/l, serum bilirubin less than 1.25 x upper limit of normal (ULN), serum transaminase less than 3 x ULN, serum ALP less than 5 x ULN
8. Fit to receive all study treatments
9. Able to comply with oral medication
10. Easter Cooperative Oncology Group (ECOG) performance status 0 or 1
11. Informed consent
12. Male and female, aged over 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
82

Key exclusion criteria
1. Previous chemotherapy
2. Previous radiotherapy to the pelvis

3. Patients who have very significant small bowel delineated within the radiation fields
4. Current or impending rectal obstruction, metallic colonic stent in situ
5. Pelvic sepsis
6. Uncontrolled cardiac, respiratory or other disease, or any serious medical or psychiatric disorder that would preclude trial therapy or informed consent
7. Known dihydropyrimidine dehydrogenase deficiency
8. Pregnant, lactating or women of childbearing potential not using adequate contraception
9. World Health Organization (WHO) performance greater than 2
10. Gastrointestinal disorder which would interfere with oral therapy or oral bioavailability
11. Patients unsuitable for surgery because of co-morbidity or coagulation problems
12. Participation in other studies except genetic studies such as NSCCG

Date of first enrolment
30/03/2009

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cancer Trials Office
-
London
England
W1T 4TJ

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

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

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/08/2017	01/10/2026	Yes	No
Abstract results		20/01/2014		No	No
Abstract results		01/09/2015		No	No
Abstract results		01/11/2017		No	No
Abstract results		01/09/2012	01/10/2026	No	No
Basic results				No	No
Protocol file		07/05/2010		No	No