

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

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/05/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Currently as of 08/03/2019:

<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>

Previously:

<https://www.cancerhelp.org.uk/trials/a-trial-looking-at-cetuximab-capecitabine-and-irinotecan-with-radiotherapy-before-surgery-for-cancer-of-the-rectum>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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/irinotecan/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/m² 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/m² 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/m² one week before the commencement of radiotherapy and then at 250 mg/m² 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/m² bd for 5 days per week on the days of radiotherapy only. In addition, they will receive IV irinotecan at 60 mg/m² 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/m² one week before the commencement of radiotherapy and then at 250 mg/m² 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, irinotecan, 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 $1.5 \times 10^9/l$
7. Platelets greater than or equal to $100 \times 10^9/l$, 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. Eastern 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. Magnetic 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 $1.5 \times 10^9/l$
7. Platelets greater than or equal to $100 \times 10^9/l$, 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. Eastern 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

Adult

Lower age limit

18 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

United Kingdom

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****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	conference abstract	20/01/2014		No	No
Abstract results	conference abstract	01/09/2015		No	No
Abstract results	conference abstract	01/11/2017		No	No
Basic results				No	No
Protocol file		07/05/2010		No	No