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

Submission date	Recruitment status	[_] Prospectively registered
23/04/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/05/2019	Cancer	

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

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Additional identifiers

EudraCT/CTIS number
2007-006701-25

IRAS number

ClinicalTrials.gov number

NCT00972881

Secondary identifying numbers
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

Study design
Randomised interventional treatment 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
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 measure
Histologically confirmed R0 resection rate, measured at surgery when the tumour is resected (captured on Surgery CRF)

Secondary outcome measures
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

Overall study start date
30/03/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned sample size: 80; UK sample size: 80

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
England

United Kingdom

Study participating centre
Cancer Trials Office
London
United Kingdom
W1T 4TJ

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
United Kingdom
WC1E 6BT

Sponsor type
Government

Website
http://www.ucl.ac.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, 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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Protocol file		07/05/2010		No	No
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