

Erbitux in preoperative chemo-radiotherapy followed by excisional surgery

Submission date 12/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/05/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/07/2024	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-giving-biological-therapy-as-well-as-combined-chemotherapy-and-radiotherapy-before-surgery-cancer-back-passage-xerxes>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2004-001926-26

Protocol serial number

1680

Study information

Scientific Title

Examining the role of Early Neoadjuvant and Synchronous Erbitux in Preoperative Chemo-Radiotherapy using Xeloda followed by Excisional Surgery

Acronym

XERXES

Study objectives

This is a multicentre pilot trial to establish the role of intravenous cetuximab when added to a schedule of capecitabine plus pelvic radiation in patients who have locally advanced primary rectal cancers. Cetuximab will be given by intravenous (iv) infusion at a loading dose of 400 mg/m² and subsequently at 250 mg/m² weekly. Capecitabine will be taken twice daily (bd) by mouth at 825 mg/m² bd on Monday - Friday each week for 5 weeks during radiotherapy.

Toxicity during treatment will be evaluated and the frequency of toxicity-led dose reductions and delays will be monitored closely. The aim is to determine the toxicity for this combined modality schedule, and a preliminary assessment of efficacy for future evaluation in a randomised controlled trial. Whilst efficacy data are always limited in a small feasibility study, radiological +/- histopathological assessment in the surgical specimen will be used to provide preliminary measures of efficacy in this patient cohort.

This study offers the opportunity to obtain biopsy material on chemo-naïve patients with rectal cancer and to examine the histological and downstream effects of single agent cetuximab.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Fife and Forth Valley Research Ethics Committee, 06/04/2005, ref: 05/S0501/49

Primary study design

Interventional

Study design

Multicentre non-randomized 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

All patients receive the following:

Radiotherapy: planned total dose of 45 Gy in 25 fractions using a three or four field plan in 33 days.

Capecitabine: 825 mg/m² twice daily orally (Mon - Fri) over 5 weeks during radiotherapy.

Radical Surgery: to be undertaken ideally 6 - 10 weeks following completion of chemoradiation.

Group 1: the first 12 patients will receive cetuximab 400 mg/m² in a short iv infusion as a starting dose then a weekly dose of 250 mg/m² for 4 weeks prior to chemoradiation (days 3, 10, 17, 24).

Group 2: the subsequent 48 patients will be randomised into:

Arm A: Chemoradiotherapy only (no cetuximab)

Arm B: Cetuximab at the above doses for 4 weeks prior to chemoradiation and 5 weeks after (not during)

Study entry: registration only

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Cetuximab, capecitabine

Primary outcome(s)

1. Acute Toxicity (Grade 3 or above in defined DLT)
2. Compliance with the planned dose of radiotherapy

Assessed after the patient has had surgery.

Key secondary outcome(s)

1. Histopathological downstaging (yPT0,T1,T2 N0)
2. Histologically confirmed (R0) resection

Assessed after the patient has had surgery.

Completion date

01/04/2014

Eligibility

Key inclusion criteria

1. Adenocarcinoma of the rectum (within 15 cm of anal verge)
2. Tumour tissue available for testing of epidermal growth factor receptor (EGFR) status
3. Indication for pre-operative chemoradiotherapy with R0 resection unlikely
4. Fit for chemotherapy
5. Written informed consent for both treatment and biopsies
6. Male and female, lower age limit of 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

22

Key exclusion criteria

1. Previous radiotherapy to the pelvis
2. Previous pelvic resectional surgery (cystectomy, hysterectomy)
3. Previous chemotherapy or radiation for rectal cancer
4. Previous chemotherapy for metastatic disease
5. Patients who have very significant small bowel delineated within the radiation fields
6. Currently enrolled in any other treatment trial

Date of first enrolment

06/12/2005

Date of final enrolment

01/04/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

CR UK and UCL Cancer Trials Centre

London

United Kingdom

W1T 4TJ

Sponsor information**Organisation**

University College London (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme Ltd (MSD) (UK)

Results and Publications

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			16/05/2019	No	No
Plain English results			29/07/2024	No	Yes