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Radiotherapy, Irinotecan, Capecitabine then Excision for locally advanced rectal cancer

Submission date 05/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 05/05/2010	**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-radiotherapy-and-chemotherapy-before-surgery-for-locally-advanced-rectal-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1387

Study information

Scientific Title
A phase I/II study of Radiotherapy, Irinotecan, Capecitabine then Excision for locally advanced rectal cancer

Acronym
RICE (NWCOG - 2)

Study objectives
Phase I/II study. Phase I investigated the safety of preoperative neoadjuvant chemoradiation using radiotherapy combined with concurrent capecitabine and irinotecan for locally advanced rectal cancer before surgery, determining the recommended dose.

Phase II of the study then used the recommended dose to assess the histological downstaging efficacy of this chemoradiation regimen, together with assessment of long-term survival end points and late radiation morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approved on the 18th March 2004 (ref: 04/4/015)

Study design
Multicentre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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

Capecitabine: orally at 650 mg/m^2 twice daily (b.d.) throughout radiotherapy including weekends
Irinotecan: 60 mg/m^2 intravenous (IV) once per week during the first 4 weeks of radiotherapy
Radiotherapy: 45 Gy in 25 daily fractions over 5 weeks

Follow-up length: 36 months

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Irinotecan, capecitabine

Primary outcome measure
1. Determine safety and recommended dose of combination of radiotherapy, capecitabine and irinotecan (phase I only)
2. Histological pathological complete response rate (phase II only)

Secondary outcome measures
1. Long-term survival outcomes (phase II only)
2. Assessment of late morbidity (phase II only)

Overall study start date
11/09/2003

Completion date
20/12/2006

Eligibility

Key inclusion criteria
1. Written informed consent given to participate in the trial
2. Male or female patients aged greater than or equal to 18 years old
3. World Health Organization (WHO) performance status 0, 1 or 2
4. Histologically confirmed previously-untreated carcinoma of the rectum with distal extent within 12 cm of the anal verge using a rigid sigmoidoscope
5. Deemed to be a candidate for preoperative downstaging chemoradiation due to: T3 disease on magnetic resonance imaging (MRI) scanning with disease less than or equal to 2 mm from the edge of the mesorectum or T4 disease on MRI scanning or any T3/T4 disease on MRI scanning with the distal extent of tumour less than or equal to 5 cm from the the anal margin
6. Adequate haematology: Neutrophil count greater than 1.5 x 10^9/l, platelet count greater than 100 x 10^9/l, Hb greater than 9 g/dl. The use of blood transfusions is allowed.
7. Adequate renal and hepatic function: serum creatinine = 1.5 x upper limit of normal (ULN), serum bilirubin = 1.25 x ULN, serum alanine aminotransferase (ALT), aspartate aminotransferase (AST) and alkaline phosphatase = 2.5 x ULN

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 142; UK sample size: 142

Total final enrolment
47

Key exclusion criteria
1. Previous systemic chemotherapy
2. Previous radiotherapy to the planned exposure area
3. Those unfit for resection because of metastases
4. Any severe concurrent medical condition which would make it undesirable, in the clinician's opinion, for the patient to participate in the trial or which would jeopardise compliance with the trial protocol
5. Patients with a calculated creatinine clearance of less than 50 ml/min
6. Patients with loss of continuity of the upper gastrointestinal (GI) tract or malabsorbtion
7. Patients who have suffered a myocardial infarction within last year and/or have unstable angina, arrythmia or cardiac failure
8. Pregnancy or lactation. Patients of child bearing potential not implementing adequate contraception.
9. Previous or current malignancies at other sites, with the exception of adequately treated in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin
10. Subjects considered by the investigator to be at risk of transmitting any infection through blood or other body fluid including Acquired Immune Deficiency Syndrome (AIDS), or other sexually transmitted disease or hepatitis
11. Patient participation in other studies
12. Partial or complete bowel obstruction (though patients in whom this has been relieved with a defunctioning stoma, are permitted to enter the trial)

Date of first enrolment
11/09/2003

Date of final enrolment
20/12/2006

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
North Wales Cancer Treatment Centre
Rhyl
United Kingdom
LL18 5UJ

Sponsor information

Organisation
Conwy and Denbighshire NHS Trust (UK)

Sponsor details
Glan Clwyd District Hospital
Rhyl
Denbighshire
Wales
United Kingdom
LL18 5UJ

Sponsor type
Hospital/treatment centre

Website
http://www.cd-tr.wales.nhs.uk/

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Roche

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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	15/09/2009		Yes	No
Plain English results			25/10/2022	No	Yes