

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 ☒ 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

Contact name

Mr Arwel Lloyd

Contact details

North Wales Cancer Treatment Centre
Ysbyty Glan Clwyd
Rhuddlan Road
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Multicentre non-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

Capecitabine: orally at 650 mg/m² twice daily (b.d.) throughout radiotherapy including weekends

Irinotecan: 60 mg/m² 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(s)

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)

Key secondary outcome(s)

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

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 $1.5 \times 10^9/l$, platelet count greater than $100 \times 10^9/l$, 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 malabsorption
7. Patients who have suffered a myocardial infarction within last year and/or have unstable angina, arrhythmia 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)

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, Pfizer Inc

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., Roche Holdings, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

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