A prospective randomised open label trial of oxaliplatin/fluoropyrimidine versus oxaliplatin/fluoropyrimidine plus cetuximab pre- and post-operatively in patients with resectable colorectal liver metastasis requiring chemotherapy

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
07/06/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/07/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
21/07/2023	Cancer			

Plain English summary of protocol

http://www.cancerhelp.org.uk/trials/a-trial-looking-at-chemotherapy-with-or-without-cetuximab-for-bowel-cancer-that-has-spread-to-the-liver-but-can-be-removed-surgically-new-epoc

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-003121-82

ClinicalTrials.gov (NCT)

NCT00482222

Protocol serial number

UOS ref: 4351

Study information

Scientific Title

A prospective randomised open label trial of oxaliplatin/fluoropyrimidine versus oxaliplatin /fluoropyrimidine plus cetuximab pre- and post-operatively in patients with resectable colorectal liver metastasis requiring chemotherapy

Acronym

New EPOC

Study objectives

To determine whether the addition of an epidermal growth factor receptor (EGFR) antibody to an oxaliplatin/fluoropyrimidine regimen improves progression-free survival in patients with resectable liver metastasis from colorectal cancer undergoing liver resection.

On 04/05/2007 the target number of participants was changed from 330 to 340.

On 08/08/2008 the including and exclusion criteria were updated. The sponsor address was also updated. Details of all changes can be found in the relevant fields.

On 30/10/2013 the following changes were made to the trial record:

- 1. The anticipated end date was changed from 31/08/2011 to 01/05/2018. The trial is now closed to recruitment and patients are in follow-up for 5 years.
- 2. The target number of participants was changed from 340 to 288. Details of other changes can be found in the relevant fields.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was given a favourable ethical opinion on 01/12/2006

Study design

An open label randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colorectal cancer with liver metastases

Interventions

Experimental arm:

Oxaliplatin/fluoropyrimidine/anti-EGFR antibody for three months. Surgical resection when fit following chemotherapy, usually 3-4 weeks. Three additional months of chemotherapy when fit following surgery, usually after one month.

Control arm:

Oxaliplatin/fluoropyrimidine for three months. Surgical resection when fit following chemotherapy. Three additional months of chemotherapy when fit following surgery.

As of 04/05/2007 the anticipated start and end dates have been updated to: Anticipated start date: the study opened to recruitment on 5th February 2007 Anticipated end date: December 2014

The previous sponsor for this trial (up to 04/05/2007) was: University of Southampton (UK) Research Governance Office Legal Services Room 4033, Building 37 University Road Southampton SO17 1BJ United Kingdom

Between 04/05/2007 and 08/08/2008, the sponsor address was: Southampton University Hospitals NHS Trust (UK) Research and Development Trust Management Offices, MP18 Southampton General Hospital Southampton SO16 6YD United Kingdom The current address can be found in the sponsor section below.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Oxaliplatin, fluoropyrimidine, cetuximab

Primary outcome(s)

Progression-free survival

Key secondary outcome(s))

Current secondary outcome measures as of 30/10/2013:

- 1. Toxicity
- 2. Overall survival

Previous secondary outcome measures:

- 1. Quality of life
- 2. Toxicity
- 3. Overall survival
- 4. Cost effectiveness

Completion date

01/05/2018

Eligibility

Key inclusion criteria

Current inclusion criteria as of 08/08/2008:

- 1. Confirmed colorectal adenocarcinoma: either previous or current histologically or radiologically confirmed primary adenocarcinoma of colon or rectum, together with clinical or radiological evidence of advanced and/or metastatic disease; confirmed primary adenocarcinoma of colon or rectum
- 2. Presence of potentially resectable colorectal cancer liver metastases
- 3. Patients who are thought by the surgeon to be suboptimally resectable are included
- 4. No previous systemic chemotherapy for metastatic disease
- 5. World Health Organization (WHO) performance status 0, 1 or 2

Added as of 04/05/2007:

- 6. Baseline laboratory tests (refer to the protocol for full description)
- 7. All patients must be aged 18 years or older
- 8. Negative pregnancy test for women of childbearing potential, adequate contraception for men and women
- 9. Written informed consent
- 10. Consent to allow surplus pathological material to be analysed for translational research projects (patients may decline participation in this supplementary study and still participate in the main trial)

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Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

257

Key exclusion criteria

Patients who are unfit for the chemotherapy regimens in the protocol e.g.:

- 1. Patients with severe uncontrolled concurrent medical illness
- 2. Any psychiatric or neurological condition which is felt likely to compromise the patient's ability to give informed consent or comply with oral medication
- 3. Partial or complete bowel obstruction
- 4. Pre-existing neuropathy (> grade 1)
- 5. Patients requiring ongoing treatment with a contraindicated concomitant medication
- 6. Patients with a previous or current malignant disease which in the judgement of the treating investigator, is likely to interfere with this study treatment or assessment of response

Added as of 04/05/2007:

- 7. Patients with known hypersensitivity reactions to any of the components of the study treatments
- 8. Patients with brain metastases
- 9. Female patients who are lactating

Added as of 08/08/2008:

- 10. Patients who have received prior chemotherapy with oxaliplatin
- 11. Patients with a personal or family history suggestive of dihydropyrimidine dehydrogenase (DPD) deficiency or with known DPD deficiency
- 12. Patients who possess the KRAS mutant genotype or whose KRAS genotype status is unknown in the primary tumour

Date of first enrolment

01/08/2006

Date of final enrolment

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University Surgical Unit MP816
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

University Hospital Southampton NHS Foundation Trust (UK)

ROR

https://ror.org/0485axj58

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (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?
Results article	results	01/05/2014	11/04/2019	Yes	No
Results article	results	09/08/2016	11/04/2019	Yes	No
Results article	results	27/09/2017	11/04/2019	Yes	No
Results article	results	01/03/2020	06/02/2020	Yes	No
Other publications	Secondary analysis	20/07/2023	21/07/2023	Yes	No
Plain English results				No	Yes