ISRCTN22944367 https://doi.org/10.1186/ISRCTN22944367

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

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

ClinicalTrials.gov (NCT)
NCT00482222

Clinical Trials Information System (CTIS)
2006-003121-82

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

01/05/2018

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