

# 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

<b>Submission date</b> 07/06/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/07/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

### Contact name

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### Contact details

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## Additional identifiers

**EudraCT/CTIS number**

2006-003121-82

**IRAS number****ClinicalTrials.gov number**

NCT00482222

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

**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 measure**

Progression-free survival

### **Secondary outcome measures**

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

### **Overall study start date**

01/08/2006

### **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)

Previous inclusion criteria:

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 potential colorectal cancer resectable 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:

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### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

288

### **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**

England

United Kingdom

**Study participating centre**

**University Surgical Unit MP816**

Southampton

United Kingdom

SO16 6YD

## **Sponsor information**

**Organisation**

University Hospital Southampton NHS Foundation Trust (UK)

**Sponsor details**

R&D Office, MP18

Southampton General Hospital

Tremona Road

Southampton

England

United Kingdom

SO16 6YD

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.suht.nhs.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, CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	results	01/05/2014	11/04/2019	Yes	No
<a href="#">Results article</a>	results	09/08/2016	11/04/2019	Yes	No
<a href="#">Results article</a>	results	27/09/2017	11/04/2019	Yes	No

<a href="#">Results article</a>	results	01/03/2020	06/02/2020	Yes	No
<a href="#">Other publications</a>	Secondary analysis	20/07/2023	21/07/2023	Yes	No