

A phase II/III randomised trial comparing Epirubicin, Cisplatin and Protracted Venous Infusion (PVI) 5-Fluorouracil (5-FU) (ECF), Epirubicin, Oxaliplatin and PVI 5-FU (EOF), Epirubicin, Cisplatin and Capecitabine (ECX) and Epirubicin, Oxaliplatin and Capecitabine (EOX) in Patients with Advanced Oesophago-Gastric Cancer

Submission date 15/10/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/10/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/05/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof David Cunningham

Contact details

Royal Marsden Hospital
Downs Road
Sutton, Surrey
United Kingdom
SM2 5PT
+44 (0)20 8661 3156
david.cunningham@rmh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MREC 01/2/31

Study information

Scientific Title

Acronym

The REAL-2 Study

Study hypothesis

To compare overall and progression free survival in patients treated with these four regimens principally comparing PVI 5FU versus Capecitabine and also Cisplatin versus Oxaliplatin. The aim is to demonstrate non-inferiority between these two main comparisons.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

Advanced, oesophageal, oesophago-gastric junctional and gastric cancers.

Interventions

Treatment should commence within 28 days of baseline CT scan and may continue for up to 24 weeks with a maximum of 8 cycles of epirubicin, cisplatin or oxaliplatin.

Patients are randomised to receive: 1. ECF Regimen (5-FU, Epirubicin and Cisplatin)
2. EOF Regimen (5-FU, Epirubicin and Oxaliplatin)
3. ECX Regimen (Capecitabine, Epirubicin and Cisplatin)
4. EOX Regimen (Capecitabine, Epirubicin and Oxaliplatin)

Intervention Type

Drug

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

Epirubicin, Cisplatin and 5-Fluorouracil (5-FU) (ECF), Epirubicin, Oxaliplatin and 5-FU (EOF), Epirubicin, Cisplatin and Capecitabine (ECX) and Epirubicin, Oxaliplatin and Capecitabine (EOX)

Primary outcome measure

The primary endpoint of the study is overall survival. The study is powered to demonstrate non-inferiority of the 2 x 2 comparisons.

Secondary outcome measures

1. Response Rates
2. Toxicity
3. Duration of response and progression free survival
4. Quality of life
5. In the phase I part of the study, to establish the optimal dose of capecitabine in the regimens

Overall study start date

03/03/2000

Overall study end date

14/11/2005

Eligibility

Participant inclusion criteria

1. Histologically verified locally advanced or metastatic adenocarcinoma, squamous cell carcinoma or undifferentiated carcinoma of the oesophagus, oesophago-gastric junction, or stomach. Patients with positive resection margin or tumour within 1mm of resection margin are eligible.
2. Uni-dimensionally measurable disease, as assessed by computed tomography (CT) and magnetic resonance imaging (MRI) scan in accordance with the Response Evaluation Criteria in Solid Tumors (RECIST) guidelines; evaluable disease, for example on oesophagogastrosocopy. The only exception is patients with positive or close resection margins who will be evaluated for survival only.

3. No prior chemotherapy
4. No prior radiotherapy other than adjuvant where relapse is outside the radiotherapy fields
5. A glomerular filtration rate (GFR) of ≥ 60 ml/min by EDTA clearance or 24 hour urinary creatinine, investigators discretion. Normal serum creatinine.
6. Serum bilirubin $< 2 \times$ institutional upper limit of normal range (IULNR)
7. Patients should have a projected life expectancy of at least 3 months
8. Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2
9. No history of other malignant diseases other than adequately treated non-melanotic skin cancer or in situ carcinoma of the uterine cervix
10. Adequate bone marrow function, white blood cell count (WBC) $> 3 \times 10^9/l$, neutrophils $> 1.5 \times 10^9/l$, platelets $> 100 \times 10^9/l$
11. Written informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1000

Participant exclusion criteria

1. Medical or psychiatric condition impairing the ability to give informed consent
2. Uncontrolled angina pectoris, heart failure, clinically significant uncontrolled cardiac arrhythmias, or clinically significant abnormal electrocardiogram (ECG) or cardiac history having a left ventricular ejection fraction (LVEF) of lower limit of normal range for institution as determined by multiple gated acquisition (MUGA) scan or echocardiogram
3. Any other serious uncontrolled medical conditions
4. Any pregnant or lactating woman. Any woman of child bearing potential must have a pregnancy test prior to randomisation and must take adequate precautions to prevent pregnancy during treatment. Any man with a partner of child bearing potential must take adequate precautions to prevent pregnancy during treatment.
5. Inability to complete the quality of life questionnaire

Recruitment start date

03/03/2000

Recruitment end date

14/11/2005

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Royal Marsden Hospital
Sutton, Surrey
United Kingdom
SM2 5PT

Sponsor information

Organisation

The Royal Marsden NHS Foundation Trust (UK)

Sponsor details

Downs Road
Sutton
United Kingdom
SM2 5PT
+44 (0)20 8661 3156

Sponsor type

Not defined

Website

<http://www.royalmarsden.nhs.uk/home>

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Industry

Funder Name

Prof Cunningham's Clinical Research Fund

Funder Name

Roche Pharmaceuticals Research Grant

Funder Name

Sanofi-Aventis Research Grant

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?
Results article	results	06/06/2005		Yes	No
Results article	results	03/01/2008		Yes	No