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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

Registration date
15/10/2002

Overall study status
Completed

Last Edited
30/05/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
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

Protocol serial number
MREC 01/2/31

Study information

Scientific Title

Acronym
The REAL-2 Study

Study objectives
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)
The primary endpoint of the study is overall survival. The study is powered to demonstrate non-inferiority of the 2 x 2 comparisons.

Key secondary outcome(s))
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

Completion date
14/11/2005

Eligibility

Key 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 oesophagogastroscopy. 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 x instiutional 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 x 10^9/l, neutrophils >1.5 x 10^9/l, platelets >100 x 10^9/l
11. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key 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

Date of first enrolment
03/03/2000

Date of final enrolment
14/11/2005

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
The Royal Marsden NHS Foundation Trust (UK)

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

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