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A randomised controlled trial comparing standard chemotherapy followed by resection versus Epirubicin, Cisplatin and Xeloda (ECX) chemotherapy followed by resection in patients with resectable adenocarcinoma of the oesophagus

Submission date 23/06/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 03/08/2004	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-chemotherapy-before-surgery-for-people-with-cancer-of-the-gullet

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00041262

Protocol serial number
OE05

Study information

Scientific Title
A randomised controlled trial comparing standard chemotherapy followed by resection versus Epirubicin, Cisplatin and Xeloda (ECX) chemotherapy followed by resection in patients with resectable adenocarcinoma of the oesophagus

Study objectives
Randomised controlled phase III trial to compare pre-operative Epirubicin, Cisplatin and Xeloda (ECX) chemotherapy to standard pre-operative chemotherapy, in patients with resectable adenocarcinoma of the oesophagus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled phase III trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Resectable adenocarcinoma of the oesophagus or oesophago-gastric junction

Interventions
Patients with resectable adenocarcinoma of the oesophagus will be randomised to receive:
1. Pre-operative Epirubicin, Cisplatin and Xeloda (ECX) chemotherapy
2. Standard pre-operative chemotherapy

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Epirubicin, cisplatin, capecitabine, fluorouracil

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Histologically verified adenocarcinoma of the oesophagus or type 1 and type 2 adenocarcinoma of the oesophago-gastric junction
2. Adenocarcinoma as above, which includes disease staged as T1 N1, T2 N1, T3 N0, and T3 N1 as assessed by spiral computed tomography (CT) or endoscopic ultrasound. T4 tumours that involve only the diaphragm or crura as well as T4 tumours invading the mediastinal pleura only.
3. Tumours with nodal disease (N1) affecting the origin of the left gastric and splenic artery with the coeliac axis (hitherto staged as M1a)
4. World Health Organisation (WHO) performance status 0 or 1
5. Proven respiratory cardiac, hepatic, renal and haematological function to the following levels: forced expiratory volume in 1 second (FEV1) >1.5 litres; cardiac ejection fraction >50% of normal echocardiography; liver function tests not more than 1.5 x normal; glomerular filtration rate ≥60 ml/min; white blood cell count >3 x 10^9/l; platelets >100 x 10^9/l (from the time diagnosis of cancer was first suspected).
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
897

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/11/2004

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (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

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No
Abstract results	results	01/06/2015		No	No
Plain English results		11/11/2015	29/10/2021	No	Yes