

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/08/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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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

Study design

Randomised controlled phase III trial

Primary study design

Interventional

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 $> 3 \times 10^9/l$; platelets $> 100 \times 10^9/l$ (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