ISRCTN01852072 https://doi.org/10.1186/ISRCTN01852072

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00041262

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2004

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

Age group
Adult

Sex
Both

Target number of participants
842 (into two groups)

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
Ian Viney
MRC Centre London
Second Floor, Stephson House
158-160 North Gower Street
London
United Kingdom
NW1 2DA

Sponsor type
Research council

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, 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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

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