ISRCTN37398231 https://doi.org/10.1186/ISRCTN37398231

Randomised trial comparing the efficacy of epirubicin, cisplatin and 5-fluorouracil (FEC) to 5-fluorouracil, methotrexate and adriamycin (FAMTX) in patients with gastric and oesophageal cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 04/01/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GI33

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Oesophagus, stomach cancer

Interventions
Patients are randomised to one of two chemotherapy regimens:
1. ECF Regimen: Multi-drug chemotherapy with epirubicin, cisplatin and 5-fluorouracil (FEC). Epirubicin and cisplatin repeated every 3 weeks for eight cycles. 5-Fluorouracil to be given by continuous infusion daily via central line for 21 weeks, stopping the day after the last cycle of cisplatin and epirubicin.
2. FAMTX Regimen: Multi-drug chemotherapy with methotrexate, adriamycin and 5-fluorouracil, cycle to be repeated every 28 days for six cycles.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Cancer drugs

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1990

Completion date
16/06/1995

Eligibility

Key inclusion criteria
1. Histologically verified locally advanced or metastatic adenocarcinoma or undifferentiated carcinoma of the oesophagus or stomach
2. Bi-dimensionally measurable disease as assessed by Computed Tomography (CT), Magnetic Resonance Imaging (MRI) or radiography: evaluable disease; non-evaluable disease
3. No prior chemotherapy or radiotherapy
4. Adequate renal and hepatic function
5. Projected life expectancy of at least 3 months
6. No history of other malignant disease other than adequately treated non-melanotic skin cancer or in-situ carcinoma of the uterine cervix
7. No contraindications to treatment protocols

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1990

Date of final enrolment

16/06/1995

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
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WC2A 3PX
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Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Industry

Funder Name
Cancer Research 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

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	01/01/1997		Yes	No