

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/01/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

+44 (0)207 317 5186

kate.law@cancer.org.uk

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