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

**Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

# 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)

Study type(s)

#### 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

# 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 United Kingdom 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, Cancer Research UK (CRUK), 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

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/1997		Yes	No