

# Randomised phase II study of sequentially high dose Methotrexate and Fluorouracil combined with Epirubicin (FEMTX) versus FEMTX plus Cisplatin (FEMTX-P) in advanced gastric cancer

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/10/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr - -

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Randomised phase II study of sequentially high dose Methotrexate and Fluorouracil combined with Epirubicin (FEMTX) versus FEMTX plus Cisplatin (FEMTX-P) in advanced gastric cancer

### 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)

Hospital

### Study type(s)

Treatment

### Participant information sheet

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

### Health condition(s) or problem(s) studied

Oesophagus, Stomach Cancer

### Interventions

Patients are randomised to one of four treatment arms:

1. Arm A: Chemotherapy with FEMTX
2. Arm B: Chemotherapy with FEMTX plus Granulocyte Colony Stimulating Factor (G-CSF)
3. Arm C: Chemotherapy with FEMTX-P
4. Arm D: Chemotherapy with FEMTX-P plus G-CSF

Centres may choose to randomise to Arms A and Arm C only.

FEMTX: Chemotherapy with 5-fluorouracil, high-dose methotrexate and epirubicin plus folinic acid rescue following methotrexate, a four week cycle given for a maximum of six cycles.

FEMTX-P: Chemotherapy with 5-fluorouracil, high-dose methotrexate, cisplatin and epirubicin

plus folinic acid rescue following methotrexate, a four week cycle given for a maximum of six cycles.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Methotrexate, fluorouracil, epirubicin and cisplatin

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1996

**Completion date**

01/01/1997

**Eligibility****Key inclusion criteria**

1. Aged less than 70 years
2. Histologically confirmed locally advanced and/or metastatic gastric cancer
3. Measurable or evaluable disease
4. Karnofsky status 80-100
5. Adequate renal, hepatic and bone marrow function

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

1. Previous chemotherapy or radiotherapy
2. Pleural or peritoneal effusions which cannot be adequately drained
3. Central Nervous System (CNS) metastases
4. History of previous or concomitant malignancy except squamous or basal cell carcinoma of the

skin which has been effectively treated and carcinoma in situ of the cervix which has been treated operatively only

5. Other medical contraindications to treatment protocols

**Date of first enrolment**

01/01/1996

**Date of final enrolment**

01/01/1997

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

## **Sponsor information**

**Organisation**

Pharmacia Ltd & Upjohn (UK)

**Sponsor details**

Davy Avenue

Milton Keynes

United Kingdom

MK5 8PH

+44 (0)1908 661101

info@adreco.co.uk

**Sponsor type**

Industry

**Website**

<http://www.pharmacia.com>

**ROR**

<https://ror.org/04x4v8p40>

# Funder(s)

## Funder type

Industry

## Funder Name

Pharmacia and Upjohn Ltd (UK)

# 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