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# 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

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>30/10/2019 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] Record updated in last year |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
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**Contact details**
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## Additional identifiers

**Protocol serial number**
ICCG/8/91

## 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

## Study type(s)
Treatment

## 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-flourouracil, 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-flourouracil, high-dose methotrexate, cisplatinum 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(s)
Not provided at time of registration

## Key secondary outcome(s))

Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Not Specified

### 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
United Kingdom

England

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

# Sponsor information

**Organisation**
Pharmacia Ltd & Upjohn (UK)

**ROR**
https://ror.org/04x4v8p40

# Funder(s)

**Funder type**
Industry

**Funder Name**
Pharmacia and Upjohn Ltd (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration