

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

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

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

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-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(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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes