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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

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/10/2019	**Condition category** Cancer	[_] Individual participant data [_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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-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 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
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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