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Phase III Randomised Study of High Dose Methotrexate and 5-Fluouracil Combined with Epirubicin (FEMTX) versus No Treatment in Stage II-III Resected Gastric Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 03/12/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ICCG/7/90

Study information

Scientific Title
Phase III Randomised Study of High Dose Methotrexate and 5-Fluouracil Combined with Epirubicin (FEMTX) versus No Treatment in Stage II-III Resected 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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cancer of Oesophagus, Stomach

Interventions
1. FEMTX Regimen: Chemotherapy, FEMTX (high dose methotrexate and 5-flourouracil with epirubicin) plus folinic acid rescue repeated every 28 days for six cycles. Chemotherapy should be started within 4 weeks of surgery.

2. Control Regimen: No further treatment.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
High Dose Methotrexate and 5-Fluouracil Combined with Epirubicin (FEMTX)

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1993

Completion date
28/02/1998

Eligibility

Key inclusion criteria
1. Histologically proven adenocarcinoma of the stomach or distal oesophagus (oesophago-gastric junction provided the cardia is involved) treated by curative resection. The resection margins must be negative for tumour.
2. Pathologically stage T2, T3 or T4, T1 tumours are only included if lymph node involvement is demonstrated histologically, ie stage II or III
3. Adequate renal, hepatic and haematological function
4. No evidence of metastatic disease
5. Karnofsky score >70
6. No history of other 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
7. No previous or current non-malignant systemic disease (cardiovascular, renal, hepatic, etc) which would contraindicate the use of chemotherapy or prevent prolonged follow up

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1993

Date of final enrolment
28/02/1998

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
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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 (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