

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
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 03/12/2019	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

Dr - -

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

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 (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration