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	Recruitment status	Prospectively registered
19/08/2002	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	Individual participant data
03/12/2019	Cancer	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 United Kingdom MK5 8PH +44 (0)1908 661101 info@adreco.co.uk

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration