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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

Registration date
19/08/2002

Last Edited
03/12/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

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