

Adjuvant cyclophosphamide, methotrexate and 5-Fluorouracil (CMF) versus 5-Fluorouracil, epirubicin and cyclophosphamide (FEC) in node negative poor-risk primary breast 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 06/11/2012	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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Contact details

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Additional identifiers

Protocol serial number

ICCG/6/89

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Patients randomised to receive chemotherapy will receive CMF or FEC no sooner than 2 weeks and no later than 4 weeks following primary surgery.

Patients will receive either:

1. CMF Regimen: Chemotherapy, CMF (cyclophosphamide, methotrexate, 5-fluorouracil) repeated every 4 weeks for six cycles.
2. FEC Regimen: Chemotherapy, FEC (5-fluorouracil, 4-epidoxorubicin, cyclophosphamide) repeated every 4 weeks for six cycles.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2004

Eligibility

Key inclusion criteria

1. Aged less than 65 years
2. Histologically proven invasive adenocarcinoma axillary nodes must be histologically negative
3. Tumour is T1c to T3
4. Tumour shows one of the following features of poor prognosis:
 - 4.1. Oestrogen receptor less than or equal to 10 fmol/mg cytosol protein
 - 4.2. Grade III
 - 4.3. Vessel invasive
 - 4.4. High labelling index of S phase
 - 4.5. Aneuploidy
 - 4.6. Tumour size at least 2 cm
5. Adequate renal, hepatic and haematological function
6. No evidence of metastatic disease
7. No evidence of inflammatory carcinoma
8. Patients with bilateral malignancy or with a mass in the opposite breast, unless there is biopsy proof that it is not a malignancy, are excluded
9. Patients with findings that relate them to a category of more advanced disease are not eligible
10. Patients with clinically positive nodes in the axilla opposite the affected breast, or with palpable supraclavicular or infraclavicular nodes are considered ineligible unless there is a biopsy evidence that these are not involved with the tumour
11. No previous or concomitant malignancy, except squamous or basal cell carcinoma which has been effectively treated and carcinoma in situ of the cervix which has been treated operatively
12. No prior therapy for the present breast cancer including radiotherapy, chemotherapy, immunotherapy and/or hormonal therapy
13. No non-malignant systemic disease which would preclude their being subjected to any of the treatment options or prevent prolonged follow up
14. No active or previous cardiac disease that would preclude the use of 4-epidoxorubicin
12. No psychiatric or addictive disorders which should preclude obtaining informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2004

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