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Adjuvant 5-Fluorouracil, 4-Epidoxorubicin and Cyclophosphamide (FEC) versus Cyclophosphamide, Methotrexate and 5-Fluorouracil (CMF) in Premenopausal Node Positive Primary Breast Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 11/01/2019	**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

Protocol serial number
ICCG/2/84

Study information

Scientific Title
Adjuvant 5-Fluorouracil, 4-Epidoxorubicin and Cyclophosphamide (FEC) versus Cyclophosphamide, Methotrexate and 5-Fluorouracil (CMF) in Premenopausal Node Positive Primary Breast 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
Breast

Interventions
All patients receive either a total mastectomy or tumour excision followed by radiotherapy. Eligible patients are randomised to receive:

A. PRE-MENOPAUSAL PATIENTS
1. Regimen A: Chemotherapy, 5-fluorouracil, 4-epidoxorubicin and cyclophosphamide (FEC), repeated every 3 weeks for a total of eight cycles.
2. Regimen B: Chemotherapy, cyclophosphamide, methotrexate and 5-fluorouracil (CMF), repeated every 4 weeks for a total of six cycles.

B. POST-MENOPAUSAL PATIENTS
3. Regimen C: Chemotherapy with FEC repeated every 3 weeks for a total of eight cycles.
4. Regimen D: No chemotherapy.

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
15/04/1992

Eligibility

Key inclusion criteria
1. Aged <65 years
2. Tumour confined to the breast or breast and ipsilateral axilla and considered operable
3. At least one axillary lymph node must show evidence of tumour on histological examination
4. On clinical examination, the axillary nodes should be moveable in relation to the chest wall and neurovascular bundle, and there should be no oedema of the arm
5. Adequate renal, hepatic and haematological function
6. No previous oophorectomy for breast carcinoma
7. No evidence of metastatic disease
8. Patients with advanced disease or ulceration, erythema, infiltration of the skin and oedema are ineligible
9. No previous concomitant malignancy, except squamous or basal cell carcinoma of the skin or carcinoma in-situ of the cervix
10. No non-malignant systemic disease which would preclude the use of any treatment within the trial

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
01/01/1987

Date of final enrolment
15/04/1992

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/1996		Yes	No
Other publications	design and rationale	01/08/1993		Yes	No