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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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1987

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

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1987

Date of final enrolment
15/04/1992

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Other publications	design and rationale	01/08/1993		Yes	No
Results article	results	01/01/1996		Yes	No