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Adjuvant cyclophosphamide, methotrexate and 5-Fluorouracil (CMF) versus 5-Fluorouracil, epirubicin and cyclosphosphamide (FEC) in node negative poor-risk primary breast cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 06/11/2012	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 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-fluouracil, 4-epidoxorubicin, cyclophosphamide) repeated every 4 weeks for six cycles.

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
01/01/2003

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

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
01/01/2003

Date of final enrolment
01/01/2004

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
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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 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