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# An adjuvant randomised study comparing standard dose FE[50]C with a higher dose FE[75]C and evaluating the additional benefit of sequential hormone therapy in node positive pre-menopausal primary breast cancer

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | |
| **Last Edited**<br>05/05/2016 | **Condition category**<br>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/9/91

# Study information

### Scientific Title
An adjuvant randomised study comparing standard dose FE[50]C with a higher dose FE[75]C and evaluating the additional benefit of sequential hormone therapy in node positive pre-menopausal 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)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Breast cancer

### Interventions
1. Regimen A: chemotherapy, FE[50]C repeated every three weeks for eight cycles followed by hormonal manipulation.
2. Regimen B: chemotherapy, FE[50]C repeated every three weeks for eight cycles.
3. Regimen C: chemotherapy, FE[75]C repeated every three weeks for eight cycles followed by hormonal manipulation.
4. Regimen D: chemotherapy, FE[75]C repeated every three weeks for eight cycles.

Patient's menopausal status to be assessed post chemotherapy. Pre-menopausal patients randomised to receive hormonal manipulation are to receive a long acting Gonadotrophin Releasing Hormone (GnRH), goserelin or equivalent, every 28 days for three years. Post-menopausal patients randomised to receive hormonal manipulation are to receive tamoxifen 20 mg daily for three years.

### Intervention Type
Drug

### Phase
Not Applicable

### Primary outcome measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/2000

### Completion date
31/12/2002

## Eligibility

### Key inclusion criteria
1. Histologically proven non-metastatic breast cancer
2. Received optimal axillary node sampling (at least seven nodes must be in the axillary dissection)
3. Between one and five histologically involved axillary nodes
4. Pre-menopausal that is:
a. Last menstrual period within one year of randomisation, or
b. Oestrogen and Follicle Stimulating Hormone (FSH)/Luteinising Hormone (LH) levels compatible with ovarian function, particularly if the patient has had a hysterectomy
5. Adequate renal, hepatic and haematological function
6. No bilateral malignancy
7. No inflammatory breast carcinoma
8. No clinically positive contralateral axillary or supraclavicular nodes, unless there is biopsy evidence that these are not involved with the tumour
9. No ulceration or infiltration of the skin
10. No satellite breast or parasternal nodules
11. No oedema of the arm
12. No medical contraindications to treatment protocols

### 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**
01/01/2000

**Date of final enrolment**
31/12/2002

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**MRC Clinical Trials Unit**
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 (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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2016 | | Yes | No |