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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

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 05/05/2016	**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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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

United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
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

Study outputs

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