

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/05/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

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/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 premenopausal 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