

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

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 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

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@adresco.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