

Epirubicin plus tamoxifen versus tamoxifen alone in post-menopausal node positive 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 12/08/2008	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

Dr - -

Contact details

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Additional identifiers

Protocol serial number

ICCG/4/87

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

1. Regimen A: tamoxifen 20 mg daily for 4 years
2. Regimen B: tamoxifen 20 mg daily for 4 years plus chemotherapy, single agent epirubicin repeated every 4 weeks for six cycles

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

28/02/1998

Eligibility**Key inclusion criteria**

1. Post-menopausal as determined by:
 - 1.1. Last menstrual cycle 12 months before surgery
 - 1.2. Patients any age with previous bilateral oophorectomy
 - 1.3. Patients aged greater than 50 years who have had hysterectomy without oophorectomy as long as the reason for surgery was not a malignancy
2. Aged less than 75 years

3. Histologically proven non metastatic T1-T3 with at least one involved ipsilateral axillary node
4. Adequate renal and haematological function
5. No prior history of malignant breast tumours
6. No bilateral malignancy or inflammatory breast cancer
7. No previous or concomitant malignancy, except squamous or basal cell carcinoma of the skin which has been effectively treated or carcinoma of the cervix in situ which has been treated operatively only
8. No non malignant systemic disease
9. No definite indication for chemotherapy

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

01/01/1996

Date of final enrolment

28/02/1998

Locations**Countries of recruitment**

United Kingdom

England

Belgium

France

Greece

Netherlands

Spain

Study participating centre

UKCCCR Register Co-ordinator
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 Ltd (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	01/07/1999		Yes	No