ISRCTN14666896 https://doi.org/10.1186/ISRCTN14666896

Epirubicin plus tamoxifen versus tamoxifen alone in post-menopausal node positive primary breast cancer

Submission date	Recruitment status	[_] Prospectively registered
19/08/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/08/2008	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/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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

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 oopherectomy 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

Age group
Adult

Sex
Female

Target number of participants
604

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

Belgium

England

France

Greece

Netherlands

Spain

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Pharmacia Ltd & Upjohn (UK)

Sponsor details
Davy Avenue
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Sponsor type
Industry

Website
http://www.pharmacia.com

ROR
https://ror.org/04x4v8p40

Funder(s)

Funder type
Industry

Funder Name
Pharmacia and Upjohn Ltd (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	01/07/1999		Yes	No