ISRCTN35478997 https://doi.org/10.1186/ISRCTN35478997

A Prospective Randomised Comparison of CMF versus Sequential Epirubicin Followed by CMF as Adjuvant Chemotherapy for Women with Early Breast Cancer

Submission date
19/08/2002

Recruitment status
No longer recruiting

Registration date
19/08/2002

Overall study status
Completed

Last Edited
08/10/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/national-breast-cancer-study-of-epirubicin-as-adjuvant-therapy

Contact information

Type(s)
Scientific

Contact name
Dr - -

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BR9601

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
1. Group A: Chemotherapy, cyclophosphamide, methotrexate and 5-fluorouracil (CMF) repeated every 3 weeks for eight cycles
2. Group B: Chemotherapy, epirubicin repeated every 3 weeks for four cycles followed by CMF repeated every 3 weeks for four 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
01/01/2000

Completion date
30/04/2001

Eligibility

Key inclusion criteria
1. Histologically confirmed breast cancer
2. Histologically confirmed axillary node metastases
3. Fit to receive chemotherapy on either arm of the trial
4. Adequate hepatic, renal and bone marrow function
5. No previous chemotherapy
6. No prior or concomitant malignancy, except basal cell carcinoma or in situ carcinoma of the cervix
7. No bilateral breast tumours or locally advanced or metastatic breast cancer, including supraclavicular fossa metastases

Participant type(s)
Patient

Age group
Not Specified

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
30/04/2001

Locations

Countries of recruitment
England

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
Milton Keynes
United Kingdom
MK5 8PH
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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 (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	02/11/2006		Yes	No