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

Submission date	Recruitment status	Prospectively registered		
19/08/2002 Registration date	No longer recruiting Overall study status	Protocol		
		Statistical analysis plan		
19/08/2002	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
08/10/2012	Cancer			

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 - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

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 +44 (0)1908 661101 info@adreco.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	02/11/2006		Yes	No