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A randomised trial of epirubicin and cyclophosphamide versus epirubicin and paclitaxel in the treatment of women with metastatic breast cancer

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 07/10/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002953

Secondary identifying numbers

AB01

Study information

Scientific Title

Study objectives
To compare epirubicin and paclitaxel versus epirubicin and cyclophosphamide in metastatic breast cancer

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
Cancer

Interventions
Epirubicin and paclitaxel/epirubicin and cyclophosphamide

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
epirubicin and cyclophosphamide versus epirubicin and paclitaxel

Primary outcome measure

Progression free survival.

Secondary outcome measures
Overall survival, response, toxicity, quality of life (Fact-B Quality of Life, Questionnaire); and health economics (Cost and Resource Use Questionnaire).

Overall study start date
01/12/1996

Completion date
05/11/1999

Eligibility

Key inclusion criteria
1. Metastatic breast cancer previously untreated except in adjuvant setting
2. Exposure to anthracyclines limited
3. Treatment free interval more than 6 months
4. Normal ejection fraction

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
700

Key exclusion criteria
History of cardiac disease

Date of first enrolment
01/12/1996

Date of final enrolment
05/11/1999

Locations

Countries of recruitment
England

South Africa

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	20/11/2005		Yes	No