

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/02/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/10/2009	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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00002953

Protocol serial number
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

Study type(s)

Not Specified

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(s)

Progression free survival.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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**

United Kingdom

England

South Africa

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Medical Research Council (MRC) (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

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