

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

Contact name

Dr Barbara Uscinska

Contact details

MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002953

Secondary identifying numbers

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
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
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