

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

|                                        |                                                   |                                                      |
|----------------------------------------|---------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>28/02/2001   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>28/02/2001 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>07/10/2009       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                   | <input checked="" type="checkbox"/> Results          |
|                                        |                                                   | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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

### Primary study design

Interventional

### Study design

Randomised controlled trial

### 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, Medical Research Committee and Advisory 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 20/11/2005   |            | Yes            | No              |