

# A randomised placebo-controlled trial of epirubicin and quinidine in patients with advanced breast cancer

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/02/2012	<b>Condition category</b> 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 - -

### Contact details

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

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

B29(Scot)

# 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 placebo 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

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Breast

## Interventions

Both arms receive Epirubicin 100 mg/m<sup>2</sup> iv every 3 weeks for a maximum of eight doses. At each cycle patients also receive a 6-day course of capsules either Quinidine 250 mg or placebo.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

epirubicin, quinidine

## Primary outcome measure

Not provided at time of registration

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/01/1988

### **Completion date**

01/09/1992

## **Eligibility**

### **Key inclusion criteria**

1. Histologically proven metastatic or locally advanced disease
2. Measurable or evaluable disease
3. World Health Organisation (WHO) Performance status at least 2
4. Haemoglobin  $\geq 10$  g%
5. White Blood Count (WBC)  $> 4.0 \times 10^9/l$
6. Platelets  $\geq 100 \times 10^9/l$
7. Bilirubin within normal range
8. Not currently receiving hormone treatment
9. No prior chemotherapy for advanced disease

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

Not provided at time of registration

### **Key exclusion criteria**

Not provided at time of registration

### **Date of first enrolment**

01/01/1988

### **Date of final enrolment**

01/09/1992

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**UKCCCR Register Co-ordinator**  
London  
United Kingdom  
NW1 2DA

## **Sponsor information**

**Organisation**  
Cancer Research UK (CRUK) (UK)

**Sponsor details**  
PO Box 123  
Lincoln's Inn Fields  
London  
United Kingdom  
WC2A 3PX  
+44 (0)207 317 5186  
kate.law@cancer.org.uk

**Sponsor type**  
Charity

**Website**  
<http://www.cancer.org.uk>

**ROR**  
<https://ror.org/054225q67>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Cancer Research UK

**Alternative Name(s)**  
CR\_UK, Cancer Research UK - London, CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**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?
<a href="#">Results article</a>	results	01/09/1994		Yes	No