

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

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/02/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)**Health condition(s) or problem(s) studied**

Breast

Interventions

Both arms receive Epirubicin 100 mg/m² 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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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 ≥ 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

Healthy volunteers allowed

No

Age group

Not Specified

Sex**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**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Cancer Research UK (CRUK) (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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/1994		Yes	No