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

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

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 x10^9/l

- 6. Platelets ≥100 x 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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes