ISRCTN23196537 https://doi.org/10.1186/ISRCTN23196537

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
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
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

Primary study design
Interventional

Study design
Randomised placebo controlled trial

Study type(s)

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

Interventions
Both arms receive Epirubicin 100 mg/m^2 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