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

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 01/02/2012	**Condition category** 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

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^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 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 ≥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

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?
Results article	results	01/09/1994		Yes	No