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A Multicentre Randomised Trial of Sequential Epirubicin and Docetaxel versus Epirubicin in Node Positive Postmenopausal Breast Cancer Patients

Submission date
19/08/2002

Registration date
19/08/2002

Last Edited
22/10/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-at-treatment-for-post-menopausal-women-with-breast-cancer

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DEVA

Study information

Scientific Title
A Multicentre Randomised Trial of Sequential Epirubicin and Docetaxel versus Epirubicin in Node Positive Postmenopausal Breast Cancer Patients

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 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

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

Interventions
Arm A. Epirubicin (50 mg/m2) IV days 1 and 8, every 28 days for 6 cycles (12 doses).
Arm B. Epirubicin (50 mg/m2) IV days 1 and 8 every 28 days for 3 cycles (6 doses) followed by docetaxel (100 mg/m2) IV over 1 h, day 1 every 21 days for 3 cycles.

All estrogen receptor (ER) and/or progesterone receptor (PgR) positive patients must receive tamoxifen 20 mg od for 5 years. In selected centres, timing of start of tamoxifen is randomised between:
Arm 1. Concurrent tamoxifen
Arm 2. Sequential tamoxifen.

Patients who are ER/PgR negative may take part in the tamoxifen arms at the clinicians' discretion.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Epirubicin, Docetaxel, Tamoxifen

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/1997

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Post-menopausal, histologically confirmed node positive breast without distant metastases
2. World Health Organisation (WHO) 1 or 2
3. No evidence of significant cardiac 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
01/08/1997

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
International Collaborative Cancer Group (ICGG) (UK)

Sponsor details
Medical Oncology
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
International Collaborative Cancer Group (UK)

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?
Plain English results				No	Yes
Results article	results	20/08/2011		Yes	No