

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

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/10/2018	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-at-treatment-for-postmenopausal-women-with-breast-cancer>

Contact information

Type(s)

Scientific

Contact name

Dr N/A N/A

Contact details

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

International Collaborative Cancer Group (ICCG) (UK)

Funder(s)

Funder type

Research organisation

Funder Name

International Collaborative Cancer Group (UK)

Results and Publications

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	20/08/2011		Yes	No
Plain English results				No	Yes