







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	 Retrospectively registered
		 Protocol not yet added
Registration date 19/08/2002	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 22/10/2018	Condition category Cancer	 Raw data not yet added
		 Study completed

Plain English Summary

<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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 hypothesis

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

Condition

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

Overall study end date

31/12/2005

Eligibility**Participant 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

Participant exclusion criteria

Not provided at time of registration

Recruitment start date

01/08/1997

Recruitment end date

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