

A Randomised Trial of Adriamycin and Taxotere vs. Adriamycin and Cyclophosphamide in Breast Cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/05/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

BR 9809

Study information

Scientific Title

Study objectives

Added 12/02/10:

To compare the clinical and pathologic response rates of doxorubicin and cyclophosphamide (AC) with doxorubicin and docetaxel (AD) as primary chemotherapy in women with primary or locally advanced breast cancer.

Please note that as of 12/02/10 this record has been updated. All changes can be found in the relevant field with the above update date.

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)

Hospital

Study type(s)

Treatment

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 cancer

Interventions

1. Adriamycin 50 mg/m² intravenous (iv) 3 weekly + taxotere 75 mg/m² iv 3 weekly (NB Taxotere must be administered prior to Adriamycin)
2. Adriamycin (60 mg/m² iv) 3 weekly + cyclophosphamide (600 mg/m² iv) weekly. Maximum of 6 cycles of combination chemotherapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Doxorubicin (Adriamycin®), docetaxel (Taxotere®), cyclophosphamide

Primary outcome measure

Added 12/02/10:

Overall (complete and partial) clinical response rates

Secondary outcome measures

Added 12/02/10:

Number of relapses

Overall study start date

01/07/1999

Completion date

01/07/2002

Eligibility**Key inclusion criteria**

1. Histologically proven breast cancer (BrCa)
2. Potentially operable disease >3cm diameter, locally advanced disease (including T4 lesions) or inflammatory BrCa
3. Patients older than 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

363 (added 12/02/10; see publication)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/07/1999

Date of final enrolment

01/07/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Scottish Cancer Therapy Network (UK)

Sponsor details

Trinity Park House

South Trinity Road

Edinburgh

United Kingdom

EH5 3SQ

Sponsor type

Research organisation

Funder(s)

Funder type

Research organisation

Funder Name

Scottish Cancer Therapy Network (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?
Results article	results	01/05/2005		Yes	No