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

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 30/05/2012	**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
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/m^2 intravenous (iv) 3 weekly + taxotere 75 mg/m^2 iv 3 weekly (NB Taxotere must be administered prior to Adriamycin)
2. Adriamycin (60 mg/m^2 iv) 3 weekly + cyclophosphamide (600 mg/m^2 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 then 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