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Randomised Phase III trial of navelbine /epirubicin versus navelbine/mitozantrone versus adriamycin/cyclophosphamide as pre-operative chemotherapy in patients with more than or equal to 3 cm diameter early 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 06/06/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

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

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00004237

Protocol serial number
TOPIC2

Study information

Scientific Title
Randomised Phase III trial of navelbine/epirubicin versus navelbine/mitozantrone versus adriamycin/cyclophosphamide as pre-operative chemotherapy in patients with more than or equal to 3 cm diameter early breast cancer

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

Study type(s)
Treatment

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

Interventions
Treatment Arms: In the ratio of 1:1 -
Navelbine 25 mg/m^2 intravenous (iv) bolus day one, epirubicin 60 mg/m^2 iv bolus day one repeating at three week intervals for six courses
Adriamycin 60 mg/m^2 iv bolus day one, cyclophosphamide 600 mg/m^2 iv bolus day one repeating at three week intervals for six courses

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Navelbine/epirubicin, navelbine/mitozantrone and adriamycin/cyclophosphamide.

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2002

Eligibility

Key inclusion criteria
1. Histologically proven breast cancer (incisional specimen or tru-cut biopsy)
2. Upper age limit 70 years
3. Potentially operable primary breast cancer more than or equal to 3 cm in diameter (maximum). (Patients with tumours more than or equal to 2 cm may also be included where chemotherapy is deemed appropriate and the patients would otherwise require radical surgery)
4. White Blood Cell (WBC) count more than 3.0 x 10^9/l, platelets more than 150 x 10^9/l
5. No evidence of metastatic disease (routine chest X-ray [CXR], biochemistry). Other investigations, e.g. bone scan, liver ultrasound, are only required for symptoms and/or abnormal biochemistry
6. World Health Organisation (WHO) performance Status zero to one
7. Normal liver function (Billirubin, transaminases, creatinine less than or equal to 1.5 x upper limit of normal value)
8. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1998

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
The Institute of Cancer Research (UK)

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Cancer Research (UK)

Alternative Name(s)
Institute of Cancer Research - CIHR, CIHR Institute of Cancer Research, L'Institut du cancer, L'Institut du cancer (IC), The Institute of Cancer Research (ICR), ICR, ICR - CIHR, IC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2005		Yes	No