

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 ☒ 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
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Contact details
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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

Primary study design

Interventional

Study design

Randomised controlled trial

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/m² intravenous (iv) bolus day one, epirubicin 60 mg/m² iv bolus day one repeating at three week intervals for six courses

Adriamycin 60 mg/m² iv bolus day one, cyclophosphamide 600 mg/m² 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 $3.0 \times 10^9/l$, platelets more than $150 \times 10^9/l$
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