

Prospective randomised evaluation of high-intensity chemotherapy with peripheral blood progenitor support in patients with high risk 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 type="checkbox"/> Results
Last Edited 15/12/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BR9405

Study information

Scientific Title

Prospective randomised evaluation of high-intensity chemotherapy with peripheral blood progenitor support in patients with high risk 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

1. High Dose Arm: Induction chemotherapy with single agent doxorubicin (adriamycin), treatment to be repeated every 3 weeks for four cycles. Induction chemotherapy to be followed by high dose chemotherapy, cyclophosphamide then cyclophosphamide and thiotepa, with stem cell support.

2. Conventional Arm: Induction chemotherapy with single agent doxorubicin, treatment to be repeated every 3 weeks for four cycles followed by conventional cyclophosphamide, methotrexate and 5-fluorouracil (CMF) repeated every 3 weeks for eight cycles.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Doxorubicin (adriamycin), cyclophosphamide, thiotepa, methotrexate, 5-fluorouracil

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/1999

Eligibility

Key inclusion criteria

1. Aged >18 years (usually <55 years).
2. Histologically proven operable stage II or IIIA breast cancer with an involvement of at least four lymph nodes
3. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
4. Confirmed normal haematological and biochemical parameters
5. Free from overt metastatic disease
6. No other malignancy, except basal cell carcinoma of the skin or in-situ carcinoma of the cervix
7. Fit to receive treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1997

Date of final enrolment

30/06/1999

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom
NW1 2DA

Sponsor information

Organisation

Amgen Limited (UK)

ROR

<https://ror.org/02gvvc992>

Funder(s)

Funder type

Industry

Funder Name

Amgen (UK)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration