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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	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/12/2015	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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