

High Dose Therapy in Poor-Risk Primary 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 26/03/2020	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

Contact name
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Contact details
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Additional identifiers

Protocol serial number
ICCG/10/92

Study information

Scientific Title
High Dose Therapy in Poor-Risk Primary 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)

Not Specified

Health condition(s) or problem(s) studied

Breast cancer

Interventions

1. Regimen A: Chemotherapy, 5-fluorouracil, epirubicin and cyclophosphamide (FEC), one 3 week cycle, then FEC repeated every 4 weeks for five cycles.

2. Regimen B: Chemotherapy, FEC one 3 week cycle, then FEC repeated every 4 weeks for five cycles followed by high dose therapy with cyclophosphamide, thiotepa and carboplatin and peripheral blood stem cell support.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

28/09/2001

Eligibility

Key inclusion criteria

1. Complete prior resection of tumour and axillary node clearance
2. Histologically proven T1-T4 primary breast cancer with at least four involved nodes in the axilla
3. Adequate local therapy as defined in the protocol
4. Aged <60 years
5. No previous malignancy or evidence of metastatic disease
6. Fit to receive treatment

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

01/01/1999

Date of final enrolment

28/09/2001

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

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