ISRCTN52623943 https://doi.org/10.1186/ISRCTN52623943

High Dose Therapy in Poor-Risk Primary Breast Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 26/03/2020	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/01/1999

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

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Amgen Limited (UK)

Sponsor details
240 Cambridge Science Park
Cambridge
United Kingdom
CB4 4WD

Sponsor type
Industry

Website
http://www.amgen.com

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration