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A blinded randomised multicentre study to evaluate fixed dose single administration filgrastim-SD/01 vs daily filgrastim as an adjuvant to chemotherapy Stage II or III/IV 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 17/11/2015	**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
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C142

Study information

Scientific Title
A blinded randomised multicentre study to evaluate fixed dose single administration filgrastim-SD/01 vs daily filgrastim as an adjuvant to chemotherapy Stage II or III/IV 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
Blinded randomised multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast Cancer

Interventions
1. Filgrastim 5 mg/kg/day 0.3 mg/ml
2. Filgrastim - SD/01 0.6 ml (of a 10 mg/ml solution)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
filgrastim

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/1999

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Can be chemotherapy naive and/or have no more than one previous regimen of chemotherapy for metastatic disease
3. Blood results within acceptable range

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/1999

Date of final enrolment
31/12/2005

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