

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	<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 17/11/2015	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

Contact name
Dr - -

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