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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

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|---|---|---|
| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>17/11/2015 | **Condition category**<br>Cancer | [ ] Individual participant data<br>[ ] 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**
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

### Study type(s)
Not Specified

### 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(s)
Not provided at time of registration

### Key secondary outcome(s))
Not provided at time of registration

### 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

### 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
01/11/1999

### Date of final enrolment
31/12/2005

## 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