# 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

Recruitment status	☐ Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Cancer	Record updated in last year
	No longer recruiting  Overall study status  Completed  Condition category

# **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

#### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes