Granulocyte Colony-Stimulating Factor (“G-CSF”): Patient profiles, Scheduling Patterns and Clinical Outcomes

First published: 20/01/2021

Last updated: 21/02/2025

Study Finalised

Administrative details

EU PAS number

EUPAS38906

Study ID

45192

DARWIN EU® study

No

Study countries

United States

Study description

This study is a retrospective cohort study assessing patient characteristics, scheduling patterns and clinical outcomes among patients with a diagnosis of breast cancer, colorectal cancer, non-Hodgkin’s lymphoma (NHL), non-small cell lung cancer (NSCLC), or ovarian cancer, treated with pegfilgrastim in the US Oncology network (USON) between January 1, 2018 and October 31, 2019, with follow-up until December 31, 2019. This study proposes to describe real-world patient profiles, treatment patterns and clinical outcomes with use of the different G-CSF products in USON clinics. All study data will originate from the electronic healthcare record (EHR) of the USON. There are 2 phases in this study. The objective of the Phase 1 analysis will be to describe treatment scheduling patterns with pegfilgrastim among the study population. The objective of Phase 2 will be to describe clinical outcomes and resource utilization by conducting a chart review.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Multiple centres: 400 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/06/2020

Study start date

Planned: 31/10/2020

Actual: 31/10/2020

Data analysis start date

Planned: 15/01/2021

Actual: 15/01/2021

Date of final study report

Planned: 31/12/2021

Actual: 14/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original pegfilgrastim 20200230 .pdf (3.31 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to understand the patient profiles, scheduling patterns and clinical outcomes among patients with breast cancer, colorectal cancer, ovarian cancer, NHL or NSCLC treated with pegfilgrastim in the US community setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Neulasta Onpro

Study drug International non-proprietary name (INN) or common name

PEGFILGRASTIM

Anatomical Therapeutic Chemical (ATC) code

(L03AA13) pegfilgrastim

pegfilgrastim

Medical condition to be studied

Breast cancer

Colorectal cancer

Ovarian cancer

Non-Hodgkin's lymphoma

Non-small cell lung cancer

Population studied

Short description of the study population

Adult patients with a diagnosis of breast cancer, colorectal cancer, NHL, NSCLC, or ovarian cancer, treated with pegfilgrastim within US Oncology Network (USON) clinics during January 1, 2018 and October 31, 2019, with follow-up until December 31, 2019.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Breast cancer, colorectal cancer, non-Hodgkin’s lymphoma, non-small cell lung cancer, or ovarian cancer patients

Estimated number of subjects

15443

Study design details

Outcomes

Phase 1: • Patient demographics and clinical disease characteristics • Scheduling patterns with pegfilgrastim Phase 2 • Scheduling patterns with pegfilgrastim • Clinical outcomes among patients initiating pegfilgrastim • Recourse utilization (hospitalization and ER visits) among patients initiating pegfilgrastim

Data analysis plan

Descriptive analyses will be conducted to evaluate the demographic, clinical and treatment characteristics of the overall study population. Descriptive statistics will be used to summarize clinical outcomes and resource utilization among patients selected for chart review in Phase 2. No multivariable statistical analyses will be conducted (e.g. multivariable logistic regression). Results will be reported in aggregate using SAS® 9.4 (SAS Institute Inc. Cary, NC, US). All results will be reported at patient-level (stratified by optimal, sub-optimal or missed appointments for pegfilgrastim) and cycle-level (stratified by

chemotherapy cycle 1-6). Data from all sources and any derived variables will be merged into one master dataset for analysis. Data will be handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH).

Documents

Study results

20200230 - GCSF Scheduling Patterns - ORSR Abstract v011222 (003)_Redacted.pdf (512.47 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Electronic healthcare record (EHR) of the USON, iKM and Limited Access Death Master File (LADMF) and the Social Security Death Index

Data sources (types)

Electronic healthcare records (EHR)

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No