Users of pegfilgrastim less than or equal to 13 years of age (20200114)

First published: 25/03/2020

Last updated: 25/09/2020

Study Finalised

Administrative details

EU PAS number

EUPAS34153

Study ID

37383

DARWIN EU® study

No

Study countries

United States

Study description

To describe the frequency (n, %) of pegfilgrastim-use in pediatric patients ages less than or equal to 13 and within a subset of patients aged < 2, stratified by calendar year and place-of-service for administration of pegfilgrastim.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

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
Planned: 02/03/2020

Actual: 02/03/2020

Study start date
Planned: 03/03/2020

Actual: 03/03/2020

Data analysis start date
Planned: 16/03/2020

Actual: 16/03/2020

Date of final study report
Planned: 31/08/2020

Actual: 25/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS34153-35209.pdf (303.73 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Among pediatric patients ages ≤ 13 years and a subset of patients ages < 2 years, describe the frequency of users of pegfilgrastim, stratified by calendar year (2013 -2018) and stratified by place-of-service of pegfilgrastim

administration.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive, retrospective analysis

Study drug and medical condition

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

PEGFILGRASTIM

Population studied

Short description of the study population

Among the patients enrolled in the IBM MarketScan database, patients who received their first, incident, administration of pegfilgrastim from 01 January 2013 to
31 December 2018 were considered for analysis.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

600

Study design details

Outcomes

Use of Pegfilgrastim, Place-of-service of administration of Pegfilgrastim

Data analysis plan

The frequency (n,%) will be calculated for pediatric patients exposed to Neulasta that are ages ≤13, a subset of patients that are aged < 2, patients by individual ages (<1, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13), patients aged 0 -< 2, 2 - 5, 6 – 10, 11-13.

Documents

Study results

20200114_Observational Research Study Report.pdf (2.68 MB)

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 sources (types)

Administrative healthcare records (e.g., claims)

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