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

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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: 21/02/2024
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?	
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:	

Main study objective:

Secondary use of data

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 namePEGFILGRASTIM

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