# Users of pegfilgrastim less than or equal to 13 years of age (20180440) (Users of pegfilgrastim =< 13 years)

First published: 21/12/2018

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Study



# Administrative details

EU PAS number		
EUPAS27161		
Study ID		
29286		
DARWIN EU® study		
No		
Study countries		
United States		

**Study description** 

On 08 November 2018, FDA requested following information from Amgen: "Describe the trends and use of Pegfilgrastim Injection in U.S. pediatric patients weighing less than 45 kg (using  $\leq$ 13 years of age as a surrogate for weight) in the last 3 years". We will use the MarketScan commercial claims database to identify users of pegfilgrastim as patients who received their first administration of pegfilgrastim between 01 Jan 2013 and 31 Dec 2017 without any prior use of pegfilgrastim. Users of pegfilgrastim will be identified in the database as patients with at least one claim with HCPCS code ("J2505", "C9119", "S0135") or at least once claim with NDC code ("54868522900", "55513019001", "55513019201") for pegfilgrastim. The results will be stratified by age at first administration ( $\leq$ 13 y vs. >13 y) and reported by 12-month intervals

#### **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: 14/12/2018

Actual: 14/12/2018

# Study start date

Planned: 14/12/2018

Actual: 14/12/2018

### Data analysis start date

Planned: 14/12/2018

Actual: 14/12/2018

#### **Date of final study report**

Planned: 15/03/2019

Actual: 03/03/2019

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Amgen

# Study protocol

20180440\_01.02.06 Public Redacted Protocol Ver 1.0 English.pdf (385.02 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

# 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:

Describe the users of pegfilgrastim between 01/01/2013 and 01/01/2017, stratified by age  $\leq 13$  y vs. > 13 y and calendar year

# Study Design

#### Non-interventional study design

Cohort

Other

# Non-interventional study design, other

Retrospective data 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

Users of pegfilgrastim identified as patients who received their first administration of pegfilgrastim between 01 Jan 2013 and 31 Dec 2017 without any prior use of pegfilgrastim from IBM Truven MarketScan Commercial Claims Database, United States.

#### Age groups

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

#### **Estimated number of subjects**

100000

# Study design details

#### Data analysis plan

In the MarketScan database, users of pegfilgrastim will be identified as patients who received their first administration of pegfilgrastim between 01 Jan 2013 and 31 Dec 2017 without any prior use of pegfilgrastim. Users of pegfilgrastim will be identified in the database as patients with at least one claim with HCPCS code ("J2505", "C9119", "S0135") or at least once claim with NDC code

("54868522900", "55513019001", "55513019201") for pegfilgrastim. There will be no continuous enrollment required for users of pegfilgrastim. The age of users of pegfilgrastim will be defined as the difference between year of first pegfilgrastim administration and year of birth (date of birth is not available in the database). The results will be stratified by age at first administration ( $\leq$ 13 y vs. > 13 y) and reported by 12-month intervals.

# **Documents**

#### **Study results**

20180440 ORSR abstract for ENCePP.pdf (1.02 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**

Unknown