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

First published: 21/12/2018

Last updated: 01/04/2024

Study Finalised

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 ≤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 (≤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 ≤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 (≤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