Prophylactic pegfilgrastim to prevent febrile neutropenia among patients receiving Q2W chemotherapy regimen: A systematic review of efficacy, effectiveness, and safety (20190355) (Pegfilgrastim in Q2W regimen: A systematic review)

First published: 16/11/2019

Last updated: 07/12/2020

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38452

EU PAS number

EUPAS31967

Study ID

38452

DARWIN EU® study

No

Study countries

- [ ] United Kingdom
- [ ] United States

Study description

Febrile neutropenia (FN) following myelosuppressive chemotherapy is a potentially life-threatening complication and is associated with loss of treatment efficacy because of dose delays, and dose reductions. To prevent FN, the National Comprehensive Care Network (NCCN) guidelines recommends prophylactic use of granulocyte colony stimulating factor (G-CSF) for patients receiving a chemotherapy regimen associated with high risk of developing FN (≥ 20%) or those receiving regimens with intermediate-risk of FN (10-20%) and have at least one patient-level risk factor. Pegfilgrastim is a long-acting G-CSF that is administered once per cycle and is the most commonly used G-CSF in the US. The US prescribing information for pegfilgrastim specifies that Neulasta should not be administered in the period between 14 days before and 24 hours after administration of myelosuppressive chemotherapy. This restriction was placed because of the potential for an increase in sensitivity of rapidly dividing myeloid cells stimulated by pegfilgrastim to myelosuppressive chemotherapy. However, this restriction precludes the prophylactic use of pegfilgrastim among several Q2W chemotherapy regimens associated with high or intermediate risk for FN. The European label for pegfilgrastim does not include the 14-day exclusion period for Neulasta prior to chemotherapy, only exclusion in the 24 hours after cytotoxic chemotherapy is administered. The latest NCCN guidelines recommend that there should be at least 12 days between the dose of pegfilgrastim and the next cycle of chemotherapy supporting the use of prophylactic pegfilgrastim in patients receiving Q2W regimens. This is

consistent with the guidelines of the European Organisation for Research and Treatment of Cancer (EORTC). The objective of this review is to provide a single-source information for oncologists and payers to make evidence-based decisions.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 2 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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: 13/08/2019

Actual: 13/08/2019

Study start date

Planned: 15/12/2019

Actual: 27/11/2019

Data analysis start date

Planned: 01/01/2020

Actual: 10/12/2019

Date of final study report

Planned: 31/10/2020

Actual: 07/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.02.06 Public Redacted Protocol Ver 1.0 2019-10-08 English.pdf(332.83 KB)

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Among patients with Q2W regimens with high or intermediate risk for FN, systematically review the evidence regarding risk of1) FN2) grade 1-4 neutropenia 3) all-cause hospitalization4) dose delays or dose reductions5) adverse events, and6) mortalityfor patients receiving prophylactic pegfilgrastim versus no prophylactic pegfilgrastim

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

PEGFILGRASTIM

Medical condition to be studied

Febrile neutropenia

Population studied

Short description of the study population

Patients diagnosed with non-myeloid malignancy and treated with a Q2W chemotherapy regimen with high (>20%) or intermediate (10-20%) risk for Febrile neutropenia (FN) and receiving prophylactic pegfilgrastim.

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

Non-myeloid malignancy patients

Estimated number of subjects

0

Study design details

Outcomes

FN: defined as an ANC of < 0.5 × 109/L, or a count of < 1.0 × 109/L that is predicted to fall to < 0.5 109/L within 48 hours, with fever or clinical signs of sepsis. OR defined as an in-patient stay with a diagnosis claim for neutropenia or fever or infection,We will not exclude studies if the FN definition is a variant of the commonly used definitions presented above.

Data analysis plan

This review will include randomized trials and observational studies of patients diagnosed with non-myeloid malignancies receiving Q2W myelosuppressive chemotherapy regimen and a primary prophylactic pegfilgrastim. Comparators will include “no primary prophylactic pegfilgrastim”, “primary prophylaxis with other G-CSF”, or “placebo”. We will also include studies where comparator is patients receiving Q3W chemotherapy regimens with primary prophylactic pegfilgrastim. Only publications that address relevant outcomes such as FN, grade 3 or 4 neutropenia, all-cause hospitalization, dose delays or dose reductions, adverse events, or mortality will be included. Systematic reviews that include studies of patients receiving Q2W chemotherapy regimens with primary prophylactic pegfilgrastim will also be reviewed for additional data that include the relevant outcomes.

Documents

Study results

20190355_Observational Research Study Report Published Report_Redacted.pdf(354.02 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Ovid, MEDLINE, Embase, and Cochrane Reviews databases

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