A non-randomized, prospective, multicenter, observational, post-authorization study to assess the efficacy of Pelgraz® (pegfilgrastim) in the primary prevention of febrile neutropenia in patients receiving high risk myelosuppressive chemotherapy (ACCPEG1)

First published: 03/02/2020

Last updated: 22/06/2022

Study Ongoing

Administrative details

EU PAS number

EUPAS31084

Study ID

47840

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy

Study description

The study is planned as an observational, prospective, study with the objective to assess the efficacy of Pelgraz® in patients receiving myelosuppressive chemotherapy (CTH) for the primary prevention of febrile neutropenia (FN). Additional aim is the assessment of the safety and the utilization pattern of Pelgraz® in patients receiving myelosuppressive CTH. The study will be conducted in multiple European clinical practices. The selection of study sites will be based on the experience of the site in conducting clinical trials and administering myelosuppressive CTH.

Study status

Ongoing

Research institutions and networks

Institutions

Europharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

JERZY CHUDEK europharma@europharma.edu.pl

Study contact

europharma@europharma.edu.pl

Primary lead investigator

JERZY CHUDEK

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2019

Actual: 15/01/2019

Study start date

Planned: 03/02/2020

Actual: 11/02/2020

Date of final study report

Planned: 31/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Accord Healthcare Limited

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

Primary Objective: Assessment of the effectiveness of Pelgraz® in the primary prevention of FN in patients with solid tumors, NHL and HL receiving myelosuppressive CTH with a risk of FN of 10-20% and additional individual risk factors or ≥20%. Secondary Objective: Assessment of safety and utilization

pattern of Pelgraz® in patients receiving myelosuppressive CTH in the whole group and the subgroup

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

PELGRAZ

Population studied

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)

Estimated number of subjects

300

Study design details

Data analysis plan

Mean, standard deviation, median, range, quartiles (continuous data), and counts and percentages (categorical data) will be calculated for baseline demographic and cancer characteristics. All the evaluation criteria mentioned above will be estimated for each CTH cycle and presented for all the cycles separately. The overall AE incidence will be summarized in terms of patient counts and percentages over the entire follow-up period, 95% confidence intervals (CIs) will also be estimated

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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