

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

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### Study ID

47840

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### DARWIN EU® study

No

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## Study countries

- ☐ France
  - ☐ Germany
  - ☐ Italy
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## 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.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

**Europharma**

**First published:** 01/02/2024

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**Institution**

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

JERZY CHUDEK

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 15/01/2019

Actual: 15/01/2019

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**Study start date**

Planned: 03/02/2020

Actual: 11/02/2020

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**Date of final study report**

Planned: 31/12/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **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  $\geq 20\%$ . 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

### **Medicinal product name**

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)

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### **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

### 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)

[Other](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No