PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Prospective, non-interventional, open-label study on the prophylactic use of a pegylated filgrastim (Pelgraz®) to reduce the duration of neutropenia and the incidence of febrile neutropenia under conventional chemotherapy for the treatment of haematological malignancies and solid tumors

Trial Acronym

PROOF

URL of the trial

[---]*

Brief Summary in Lay Language

Prospective, non-interventional, open-label study on the prophylactic use of a pegylated filgrastim (Pelgraz®) to reduce the duration of neutropenia and the incidence of febrile neutropenia under conventional chemotherapy for the treatment of haematological malignancies and solid tumors.

Brief Summary in Scientific Language

The aim is to examine the frequency of occurrence of febrile neutropenia under primary prophylaxis with pegfilgrastim (Pelgraz®) considering the day of Pelgraz® administration.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017218**
- Date of Registration in DRKS: **2019/05/29**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**

DRKS-ID: **DRKS00017218**
Date of Registration in DRKS: **2019/05/29**
Date of Registration in Partner Registry or other Primary Registry: **[---]***
Investigator Sponsored/Initiated Trial (IST/IIT): **no**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2018375 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

Health condition or Problem studied

- Free text: **febrile neutropenia**
- ICD10: **D70.0 - [generalization D70: Agranulocytosis]**

Interventions/Observational Groups

- Arm 1: **Patients (≥18 years) with haematological malignancies or solid tumors (with the exception of chronic myelogenous leukemia and myelodysplastic syndrome) and with an overall risk for febrile neutropenia of > 20 % or an intermediated risk between ≥10 to 20 % with individual risk factors who are routinely and prophylactically treated with Pelgraz® according to the SmPC either as an initial G-CSF or as a switch from another G-CSF.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The aim is to examine the frequency of occurrence of febrile neutropenia under primary prophylaxis with pegfilgrastim (Pelgraz®) considering the day of Pelgraz® Administration.

Secondary Outcome

Determination of the percentage of patients developing a febrile neutropenia and / or where the dose of chemo therapy of the next cycle is reduced or the next therapy cycle is postponed, considering the day of Pelgraz® administration. Determination of the frequency of febrile neutropenia under secondary prophylaxis with pegfilgrastim (Pelgraz®) considering the day of Pelgraz® administration. Determination of the percentage of patients receiving p.o / i.v. anti-infective agents and / or being hospitalized due to febrile neutropenia or infections, considering the day of Pelgraz® administration. Determination of the frequency of switches from another G-CSF to Pelgraz® and the reasons therefore. Validity of predictive factors for febrile neutropenia (with hospitalization) or infections (with hospitalization) under G-CSF prophylaxis based on the following criteria:
• Chemotherapy (dose-dense versus not-dose-dense with a cycle of more than 14 days)
• Patients with the following risk factors:
o Age > 65 years
o Advanced cancer
o Previous febrile neutropenia
o Female
o Reduced general condition (high ECOG, low Karnofsky index)
o poor nutritional status
o limited immune function
Frequency of occurrence of adverse drug reactions compared to the information described in the SmPC for Pelgraz®.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Berlin**
- Doctor's Practice **Bonn**
- Doctor's Practice **Brandenburg**
- Doctor's Practice **Chemnitz**
- Doctor's Practice **Dresden**
- Doctor's Practice **Erfurt**
- Doctor's Practice **Fürstenwalde**
- Doctor's Practice **Heidenheim**

- Doctor's Practice **Herne**
- Doctor's Practice **Hildburghausen**
- Doctor's Practice **Kaiserlautern**
- Doctor's Practice **Köln**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Lörrach**
- Doctor's Practice **Moers**
- Doctor's Practice **Mühlhausen**
- Doctor's Practice **Naunhof**
- Doctor's Practice **Plauen**
- Doctor's Practice **Rostock**
- Doctor's Practice **Scheibenberg**
- Doctor's Practice **Schorndorf**
- Medical Center **Marienkrankenhaus, Brustzentrum, Schwerte**
- Doctor's Practice **Stolberg**
- Doctor's Practice **Stralsund**
- Doctor's Practice **Ueckermünde**
- Doctor's Practice **Werdau**
- Doctor's Practice **Würselen**
- Doctor's Practice **Zittau**
- Doctor's Practice **Zwickau**
- Doctor's Practice **Bamberg**
- Doctor's Practice **Bergisch Gladbach**
- Doctor's Practice **Berlin**
- Doctor's Practice **Bernburg (Saale)**
- Doctor's Practice **Bochum**
- Doctor's Practice **Braunschweig**
- Doctor's Practice **Dassau-Roßlau**
- Doctor's Practice **Doanuwörth**
- Doctor's Practice **Dartmund**
- Doctor's Practice **Dortmund**
- Doctor's Practice **Dortmund**

- Doctor's Practice **Dresden**
- Doctor's Practice **Frechen**
- Doctor's Practice **Freudenstadt**
- Doctor's Practice **Hannover**
- Doctor's Practice **Hildesheim**
- Doctor's Practice **Krefeld**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Lohsa**
- Doctor's Practice **Ludwigsburg**
- Doctor's Practice **Mönchengladbach**
- Doctor's Practice **Mülheim an der Ruhr**
- Doctor's Practice **Neustadt/Weinstrasse**
- Doctor's Practice **Paderborn**
- Doctor's Practice **Passau**
- Doctor's Practice **Pirna**
- Doctor's Practice **Planegg**
- Doctor's Practice **Remscheid**
- Doctor's Practice **Riesa**
- Doctor's Practice **Rodgau**
- Doctor's Practice **Rostock**
- Doctor's Practice **Rostock**
- Doctor's Practice **Rostock**
- Doctor's Practice **Stuttgart**
- Doctor's Practice **Witten**
- Doctor's Practice **Würzburg**
- Doctor's Practice **Zwickau**
- Doctor's Practice **Zittau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/03/27**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2019/03/27**

- Target Sample Size: **750**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Male or female patients ≥18 years with haematological malignancies or solid tumors who receive a conventional cytotoxic chemotherapy and who are treated prophylactically with Pelgraz® according to the SmPC.

Risk of febrile neutropenia between ≥ 10% and 20% (with individual risk factors) as assessed by the attending physician or overall FN risk of > 20%.

Written informed consent given by the patient or by relatives / caregivers for the retro- and prospective collection, transfer and analysis of pseudonymized data as well as for verification of patient data during a monitoring visit.

Exclusion criteria

Hypersensitivity to pegfilgrastim or to any other ingredient of Pelgraz®

Patients with severe congenital neutropenia who develop leukemia or who show signs of leukemia

Patients with myelodysplasia or chronic myelotic leukaemia

Patients with a recent history of pulmonary infiltrates or pneumonia

For female patients: pregnancy or breastfeeding

Addresses

- **Primary Sponsor**

ACCORD Healthcare GmbH
Ms. Elen Baumann
Hansastr. 32
80686 München

Primary Sponsor

ACCORD Healthcare GmbH
Ms. Elen Baumann
Hansastr. 32
80686 München
Germany

Telephone: **089-700995137**
Fax: **[---]***
E-mail: **elen.baumann at accord-healthcare.com**
URL: **[---]***

■ **Contact for Scientific Queries**

ACCORD Healthcare GmbH
Ms. Elen Baumann
Hansastr. 32
80686 München
Germany

Telephone: **089-700995137**
Fax: **[---]***
E-mail: **elen.baumann at accord-healthcare.com**
URL: **[---]***

■ **Contact for Public Queries**

ACCORD Healthcare GmbH
Ms. Elen Baumann
Hansastr. 32
80686 München
Germany

Telephone: **089-700995137**
Fax: **[---]***
E-mail: **elen.baumann at accord-healthcare.com**
URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

ACCORD Healthcare GmbH
Ms. Elen Baumann
Hansastr. 32
80686 München
Germany

Telephone: **089-700995137**

Commercial (pharmaceutical industry, medical engineering industry, etc.)

ACCORD Healthcare GmbH
Ms. Elen Baumann
Hansastr. 32
80686 München
Germany

Telephone: **089-700995137**
Fax: **[---]***
E-mail: **elen.baumann at accord-healthcare.com**
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*