Trial Description

Title

HEXAFIL: Non-interventional study for supportive treatment of chemotherapy induced neutopenia with Filgrastim HEXAL®

Trial Acronym

HEXAFIL

URL of the trial

http://nicht vorhanden

Brief Summary in Lay Language

The aim of this non-interventional study is the systematic collection of data from the intended prophylactic and secondary-prophylactic use of Filgrastim HEXAL® to support the antineoplastic therapy of cancer patients.

Brief Summary in Scientific Language

Chemotherapy induced neutropenia are a common complication in the course of systemic antineoplastic chemotherapy of different tumor entities. For the development of chemotherapy induced neutropenia as well as the individual response to the treatment, different factors (eg, neoplasms, treatment, medical history, demographic factors) are held responsible for. The human Granulocyte-Stimulating Factor (G-CSF) is a peptide hormone and haematopoietic growth factor that is involved in promoting the proliferation and differentiation of progenitor cells to mature neutrophils. The systematic collection of data from the routine use of biosimilar Figrastim HEXAL® will allow for a more comprehensive data collection of efficacy and safety of Filgrastim HEXAL®.

Organizational Data

- DRKS-ID: **DRKS00000313**
- Date of Registration in DRKS: **2010/01/18**
- 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.: **FF99/2009 , Ethikkommission der Landesärztekammer Hessen**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1113-2795**

Health condition or Problem studied

- Free text: **chemotherapy induced neutropenia**
- ICD10: **D70.1 - message.icd10.coding.redirected.en**

Interventions/Observational Groups

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): **[---]***

Primary Outcome

Safety profile of Filgrastim HEXAL®

Secondary Outcome

Efficacy of Filgrastim HEXAL® treatment - application period of Filgrastim HEXAL® (measured as number of days applied per chemotherapy cycle); occurrence of febrile neutropenia, leukocyte count observed before the start of chemotherapy cycle (if available) and lowest leukocyte count observed during the chemotherapy cycle (if available); correlation of Filgrastim HEXAL® administration to tumor entitiy and previous therapy regimen; supportive treatment with antibiotics / fungicides ; assessment of self-administration of Filgrastim HEXAL® (s.c.) by the patients, assessment of the needle protection system; overall rating for efficacy and tolerability by the responsible physician.

Additional secundary parameters in line with the Amendment No. 1, active since 08/17/2011:
Analysis of the ANC (absolute neutrophil count) before and lowest ANC during the

observed chemotherapy cycle; intention of supportive antibiotics/antimycotics therapy

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/01/29**
- Target Sample Size: **1460**
- 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

1.) Patients undergoing antineoplastic therapy and who are treated either prophylactically or interventionally with Filgrastim HEXAL® in case of emerging neutropenia.
2.) Male and female patients at least 18 years old (no upper age limit)
3.) Signed informed consent of the patient to the collection and forwarding of pseudonymised data

Exclusion criteria

1.) Contraindication according Summary of Products Characteristics (SPC) Filgrastim HEXAL®
2.) Furthermore, patients should not be included in the non-interventional study if they fulfill at least one of the following criteria:
a.) Patients who have not signed the informed consent form
b.) Patients who have been treated with G-CSF in the current line of chemotherapy treatment
c) Female patients who are pregnant or breast-feeding
d.) Patients undergoing myelosuppressive or myeloablative therapy followed by

autologous transplantation of PBBC, and

e.) Patients who are diagnosed with myelodysplastic syndrome (MDS)
f.) Patients who are diagnosed with chronic myelogenous leukemia (CML)
g.) Patients who are diagnosed with secondary AML
h.) Patients who are scheduled for myeloablative treatment followed by bone marrow transplantation
i). Patients who are diagnosed with severe chronic neutropenia (SCN), congenital neutropenia, or idiopathic or cyclic neutropenia
j.) Patients aged < 55 year who are diagnosed with de novo AML with good cytogenetics [t(8;21), t(15;17), and inv(16)]
k.) Patients who are diagnosed with HIV
l.) Patients who are diagnosed with hereditary fructose intolerance
In line with the Amendment No. 1 (approved by CEC on 06/28/2011), active since 08/17/2011:
m). Patients who have been treated with filgrastim HEXAL® for the treatment of chemotherapy-induced neutropenia and who already participated in the non-interventional study HEXAFIL

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/06/30**

Trial Publications, Results and other documents

- Trial results **HexaFil Study Results**

** 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.*