A comparative Study on Efficacy and Safety of Lipegfilgrastim in Comparison to Pegfilgrastim in Elderly Patients With Aggressive B Cell Non-Hodgkin Lymphomas at high Risk for R-CHOP-21-induced Neutropenia (AVOID)

Purpose

The primary objective of the study is to demonstrate non-inferiority of lipegfilgrastim to pegfilgrastim for the duration of severe neutropenia in the first cycle of chemotherapy.

Resource links provided by NLM:

- Genetics Home Reference related topics: cyclic neutropenia
- MedlinePlus related topics: Lymphoma
- Drug Information available for: Pegfilgrastim
- Genetic and Rare Diseases Information Center resources: B-cell Lymphomas, Granulocytopenia, Lymphosarcoma
- U.S. FDA Resources

Further study details as provided by Teva Pharmaceutical Industries:

Primary Outcome Measures:
Duration of severe neutropenia (DSN) ANC <0.5 * 10^9/L [ Time Frame: 3 weeks ] [ Designated as safety issue: No ]
Grade 4 neutropenia measured in days

Secondary Outcome Measures:
- Incidence of febrile neutropenia (FN) (strict definition) [ Time Frame: 18 weeks ] [ Designated as safety issue: No ]
  Body temperature of >38.5°C for at least one hour and ANC<1*10^9/L
- Incidence of FN [ Time Frame: 18 weeks ] [ Designated as safety issue: No ]
  A single temperature of ≥38.3°C or ≥38.0°C for at least one hour and ANC <1 * 10^9/L
- Incidence of very severe neutropenia [ Time Frame: 3 weeks ] [ Designated as safety issue: No ]
  The occurrence of at least one incidence of ANC <0.1 * 10^9/L
- Incidence of infections [ Time Frame: 18 weeks ] [ Designated as safety issue: No ]
  Incidence and severity of infections
- Time to ANC recovery [ Time Frame: 3 weeks ] [ Designated as safety issue: No ]
  The time in days from start of chemotherapy administration until the ANC increases to ≥1.0 x 10^9/L, ≥1.5 x 10^9/L, and ≥2.0 x 10^9/L after the expected nadir
- Summary of participants with adverse events [ Time Frame: 9 Months ] [ Designated as safety issue: Yes ]

Estimated Enrollment: 150
Study Start Date: March 2014
Estimated Study Completion Date: August 2016
Estimated Primary Completion Date: March 2016 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: lipegfilgrastim subcutaneous (SC) injection of 6 mg lipegfilgrastim</td>
<td>Drug: lipegfilgrastim 6 mg Other Name: XM22</td>
</tr>
<tr>
<td>Active Comparator: pegfilgrastim SC injection of 6 mg pegfilgrastim</td>
<td>Drug: pegfilgrastim 6 mg Other Name: Neulasta®</td>
</tr>
</tbody>
</table>

Eligibility

Ages Eligible for Study: 65 Years to 85 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
1. Signed and dated Independent Ethics Committee (IEC)-approved written informed consent
2. Age ≥65 years and ≤85 years
3. Histological documentation of aggressive B cell NHL
4. Planned to receive systemic anticancer therapy with at least 6 cycles of R-CHOP-21, according to local standards
5. ECOG score ≤2
6. Life expectancy of at least 3 months
7. Adequate bone marrow, renal and hepatic function within 14 days before start of chemotherapy
8. The patient is capable of understanding and complying with parameters as outlined in the protocol
9. Women of childbearing potential (not surgically sterile or 2 years postmenopausal) must use a medically accepted method of contraception and must agree to continue use of this method for the duration of the treatment and for 30 days after discontinuation of
study drug.

10. The patient, if a man, is surgically sterile, or, if capable of producing offspring, is currently using an approved method of birth control and agrees to continued use of this method for the duration of the treatment (and for 90 days after taking the last dose of study

- Other Criteria apply, please contact the investigator for more information

Exclusion Criteria:

1. Participation in a clinical study within 30 days before randomization
2. Any chemotherapy within the last 3 months before start of chemotherapy. A prephase to reduce tumor burden prior to start of R-CHOP is allowed.
3. The patient is a pregnant or lactating woman. (Any woman becoming pregnant during the study will be withdrawn from the study.)
4. Major surgical procedure, open biopsy, or significant traumatic injury within 28 days before start of chemotherapy.
5. Active cardiac disease
6. Arterial or venous thrombotic or embolic events such as cerebrovascular accident (including transient ischemic attacks), deep vein thrombosis or pulmonary embolism within the 6 months before start of chemotherapy.
7. Ongoing infection, known history of human immunodeficiency virus (HIV) infection, tuberculosis, or chronic hepatitis B or C.
8. Patients with evidence or history of bleeding diathesis.
9. Non-healing wound, ulcer or bone fracture.
10. Renal failure requiring hemodialysis or peritoneal dialysis.
11. Any conditions that may interfere with the patient’s participation in the study or evaluation of the study results.
12. Known hypersensitivity to any of the study drugs, study drug classes, or excipients in the formulation.
13. Any illness or medical conditions that are unstable or could jeopardize the safety of the patient and his/her compliance in the study.
14. Treatment with lithium at screening or planned during the study.

- Other Criteria apply, please contact the investigator for more information

---

**Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02044276

**Contacts**

Contact: Teva US Medical Information 1-800-896-5855

[Show 55 Study Locations]

**Sponsors and Collaborators**

Merckle GmbH

**More Information**

No publications provided

**ClinicalTrials.gov Identifier:** NCT02044276

**Other Study IDs:** XM22-ONC-305, 2013-001284-23

**Study First Received:** January 21, 2014

**Last Updated:** October 29, 2014

**Health Authority:**

- France: Ministry of Health
- Germany: Ministry of Health
- Italy: Ministry of Health
- Spain: Ministry of Health

**Keyw ords provided by Teva Pharmaceutical Industries:**

- Neutropenia
- NHL
- Non-Hodgkin lymphomas
R-CHOP-21

Additional relevant MeSH terms:
Aggression
Lymphoma
Lymphoma, B-Cell
Lymphoma, Non-Hodgkin
Neutropenia
Agranulocytosis
Behavioral Symptoms
Hematologic Diseases

Immune System Diseases
Immunoproliferative Disorders
Leukocyte Disorders
Leukopenia
Lymphatic Diseases
Lymphoproliferative Disorders
Neoplasms
Neoplasms by Histologic Type

ClinicalTrials.gov processed this record on December 04, 2014