ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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ClinicalTrials.gov ID: NCT00794261

Study Identification

Unique Protocol ID:	PALM
Brief Title:	Stem Cell Mobilization With Pegfilgrastim in Lymphoma and Myeloma (PALM)
Official Title:	Assessment of the Efficacy and Tolerance, and Health Economic Study of a Single Administration of Pegfilgrastim in Lymphoma or Myeloma Patients Treated With Intensive Chemotherapy and Autologous Peripheral Stem Cell Transplantation
Secondary IDs:	ET2007 - 113

Study Status

Record Verification:	July 2010
Overall Status:	Completed
Study Start:	September 2008 []
Primary Completion:	January 2010 [Actual]
Study Completion:	June 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Centre Leon Berard
Responsible Party:	
Collaborators:	Centre Leon Berard Amgen

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: A08 - 149 Board Name: CPP SUD-EST IV (Comité de Protection des Personnes) Board Affiliation: French Ministry of Health Phone: +33 478 78 27 61 Email: maritazo@lyon.fnclcc.fr Address: Centre Léon Bérard, 28 rue Laënnec, 69373 LYON Cedex 08

Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary: The purpose of this study is to evaluate the efficacy and tolerance of a single administration of Pegfilgrastim in patients with lymphoma or myeloma receiving high-dose chemotherapy and autologous peripheral stem cell support, and to estimate the costs incurred.

Eligible patients will be randomized. The estimated inclusion period is approximately 18 months. The duration of the research is 22 months. The maximum duration of participation for each patient is 3 months.

The number of patients required in this multicentric and prospective study is 150 (13 participating centers).

This is a phase II, controlled, randomized, non comparative and open-label multicentric study.

Detailed Description: High-dose chemotherapy with autologous peripheral stem cell (PSC) transplantation is a standard consolidation treatment for the initial management of patients with myeloma treated with high-dose Melphalan, or patients with certain lymphomas or with chemosensitive relapses of Hodgkin's lymphoma (HL) or malignant non Hodgkin's lymphoma (MNHL). This procedure is associated with prolonged neutropenia and considerable morbidity. Many randomized trials have tested post-graft administration of granulocyte growth factors (granulocyte colony stimulating Factor: G-CSF) or granulocyte-monocyte growth factors (granulocyte macrophage colony stimulating Factor: GM-CSF). All have shown a reduction of neutropenia and shorter hospital stays on G-CSF or GM-CSF treatment. Different guidelines have recommended the use of growth factors after autologous stem cell transplantation. The effectiveness of growth factor treatment would be identical, whether given immediately after PSC transplantation or delayed until D5 or D7.

Pegfilgrastim is a growth factor resulting from the modification of Filgrastim by addition of a polyethylene glycol (PEG) moiety, which increases its half-life by decreasing its renal clearance. Thus, one injection is equivalent to several Filgrastim injections. Studies of Pegfilgrastim or Filgrastim efficacy on the duration of chemotherapy-induced neutropenia in patients with breast cancer or with non-small cell lung cancer or LMNH have produced equivalent results.

In haematology, Pegfilgrastim has been used for PSC mobilization. Six studies evaluating the efficacy of Pegfilgrastim compared to other G-CSF after autologous hematopoietic PSC transplantation in patients with myeloma and lymphomas have shown equivalent results. A superiority of Pegfilgrastim over other G-CSF has even been reported (though in only one randomized small-scale study).

A randomized phase II study evaluating Pegfilgrastim efficacy and tolerance in lymphoma or myeloma patients receiving PSC transplantation appears necessary to confirm or refute the potential clinical interest of the drug.

On the day of autologous PSC transplantation (D0) the patients will be randomly assigned to receive one or the other treatment strategy.

NB: Patients will receive support care, antibiotic treatments and transfusion procedures specific to each participating centre.

They will be followed-up according to recommendations for the management of this type of patients. No additional examination is planned.

Conditions

Conditions:	Lymphoma Myeloma
Keywords:	Myeloma lymphoma high-dose chemotherapy PSC infusion, autologous neutropenia thrombocytopenia hospital stay infection Autologous PSC transplantation for patients with lymphoma or myeloma treated with high-dose chemotherapy

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	None (Open Label)
Allocation:	Randomized
Enrollment:	150 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Pegfilgrastim Single subcutaneous administration of Pegfilgrastim (Neulasta® - Laboratory AMGEN) 6 mg at D5	Drug: Injection of Pegfilgrastim Single subcutaneous administration of Pegfilgrastim (Neulasta® - Laboratory AMGEN) 6 mg at D5
Active Comparator: Filgrastim Daily subcutaneous administration of Filgrastim (Neupogen® - Laboratory AMGEN) 5 µg/kg/day from D5 until recovery from aplasia (PNN > 0.5 G/L)	Drug: Injection of Filgrastim Daily subcutaneous administration of Filgrastim (Neupogen® - Laboratory AMGEN) 5 µg/kg/day from D5 until recovery from aplasia (PNN > 0.5 G/L)

Outcome Measures

Primary Outcome Measure:

1. Efficacy of a single administration of Pegfilgrastim at D5 in shortening the duration of febrile neutropenia
   [Time Frame: 100 days]

Secondary Outcome Measure:

2. Average duration of neutropenia, average duration of thrombocytopenia, number of days with temperature, number of red blood cell units and platelet concentrates transfused to the patient
   [Time Frame: 100 days]
3. Average duration of hospital stay since PSC transplantation
   [Time Frame: 100 days]

4. Number of bacterial and/or viral and/or fungal infections, average duration of antibiotic, antiviral and/or antifungal treatment
   [Time Frame: 100 days]
5. Treatment tolerance
   [Time Frame: 100 days]
6. Evaluation of treatment by Filgrastim
   [Time Frame: 100 days]
7. Evaluation of treatment costs in the two arms
   [Time Frame: 100 days]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No

Criteria: Inclusion Criteria:

- Male or female patients aged ≥ 18 years
- Patients with histologically confirmed lymphoma or myeloma
- Treatment with high-dose chemotherapy before inclusion
  - Intensification with high dose Melphalan for patients with myeloma
  - Whatever the conditioning regimen, except TBI for patients with 1st relapse of Hodgkin's lymphoma or with MNHL NB: Patients having received two intensification courses are eligible if there has been more than 100 days between courses.
- Autologous PSC transplantation at the time of inclusion
- Reinjection of ≥ 2.106 CD34/kg
- Patients hospitalized in the investigator center throughout the procedure until recovery from aplasia (PNN > 0.5 G/L)
- Mandatory affiliation with a health insurance system
- Patients able to understand, read and write French
- Signed, written informed consent

Exclusion Criteria:

- TBI during conditioning
- Severe intolerance to the growth factor under study, or hypersensitivity to one of their components
- Immunosuppressive syndrome
- Pregnant or lactating women
- Difficult follow-up
- Documented history of cognitive or psychiatric disorders
- Participation or consideration of participation in another biomedical study during the follow-up period of the present trial.

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