IFM-2015-03 - (dernière mise à jour : 03/09/2019)

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Informations générales

Titre de l'étude : Non-interventional Study Evaluating Plerixafor-based Mobilization for Salvage Autologous Hematopoietic Stem Cell Transplantation in Relapsed Myeloma

Traitement :

Type d'étude : Qualité de vie / Observationnelle

Phase : NA **Stade** : NA **Ligne(s)** :

Schéma : This is a non-interventional study; visit will be performed as usual, according to each center practices. No additional visits will be requested for the study purpose. The date for each visit and any data generated must be recorded on the appropriate eCRF.

The study will consist of 3 periods:
- An early screening period
- Autologous stem cell mobilization period using G-CSF+Plerixafor
- High dose melphalan therapy and autologous graft infusion and follow-up for12 months after salvage ASCT Inclusion visit

This visit may occur up to 28 days before Mozobil® administration. This visit will be performed during the visit of pre-transplant assessment. For the pre-transplant assessment, the procedures are performed routinely before ASCT even if the patient is not included in the study:

Stem cell mobilization phase The stem cell mobilization phase is performed according to standard practice of each participating centre.

Follow-up visits High dose melphalan administration and autologous graft infusion will be performed according to each centre standard practice. Patients will be followed according to each center practices. The follow-up of this non-interventional study will end 12 months after ASCT.

Subjects will be enrolled over a 2 years period. The total duration of the study will be 36 months

Current primary outcome:
Feasibility to collect at least 2x10e6/kg CD34+ peripheral blood cell stem cells [Time Frame: from date of Plerixafor based mobilization until the date of stem cells transplantation, an expected average of 24 hours]
Percentage of patients achieving CD34+ ? 2x10e6/kg recipient body weight in one apheresis session after stem cell mobilization

Current secondary outcomes:
- Engraftment after ASCT (neutrophil and platelets recovery) [Time Frame: Time to achieve neutrophil (>500/µl) and platelets (first of three days with>20G/l without transfusion), an expected average of 20 days]
- Time to disease progression [Time Frame: from the date of ASCT to the date of the first observation of disease progression, assessed up to 12 months follow-up]
- Duration of response [Time Frame: the time from partial response or complete response to the first documentation of disease progression, assessed up to 12 months follow-up]
- Progression free survival (PFS) [Time Frame: time from the start of treatment to the first documentation of disease progression or death from any cause during study, whichever occurs earlier, assessed up to 12 months follow-up]
- Overall Survival [Time Frame: from the date of ASCT to the date of death or the last date the patient was known to be alive whichever occurs first, assessed up to 12 months follow-up]
- Clinical Safety as measured by the type, the frequency and the severity of adverse events and laboratory abnormalities [Time Frame: 12 months follow-up]
incidence of treatment emergent Adverse event (TEAE), serious adverse event (SAE) and laboratory abnormalities using NCI common toxicity criteria

Spécialités / Localisations

Spécialité n°1 : Tissus lymphoïde, hématopoïétique et apparentés

CIM10 - Localisation n°1 : **C90** - Myélome multiple et tumeurs malignes à plasmocytes

Critères

Critères d'inclusion : - Patients aged >= 18 years,
- Relapsed myeloma according to standard criteria and eligible for a second salvage autologous transplantation. Eligibility to autologous transplantation is based on local guidelines and standard practice
- Written patient's agreement

Critères de non-inclusion : - Age > 75,
- Contraindication to autologous stem cell transplantation
- Contraindications to the use of plerixafor

Informations promoteur

Nom du promoteur : Association for Training, Education and Research in Hematology, Immunology and Transplantation (ATERHIT)

Type de promoteur : Institutionnel

Adresse : Service d'hématologie et thérapie cellulaire CHU Paris Est - Hôpital Saint-Antoine 184 rue du Faubourg Saint-Antoine 75012 PARIS FRANCE - 75012 PARIS 12

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre Hospitalier Universitaire de Lille

Adresse : 2 Avenue Oscar Lambret 59000 LILLE

Investigateur : Professeur Thierry FACON

TEC / ARC / IDE : Secrétariat de recherche - *Mail :* fanny.miquel@chru-lille.fr - *Tél :* 03.20.44.57.13

Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials (anglais) : https://clinicaltrials.gov/ct2/show/record/NCT02439476?term=NCT02439476&rank=1