ALLO-BEST

Allogreffe de cellules souches hématopoïétiques comparée au meilleur standard de traitement disponible pour les patients âgés atteints de leucémie aigüe myéloïde : Essai randomisé de phase III

Phase : III

Type d'essai : Académique / Institutionnel

Thème spécifique : Sujets Agés

Etat de l'essai : Ouvert

Objectif principal

Overall survival.

Résumé / Schéma de l'étude

Experimental : Allogeneic Hematopoietic Cell Transplantation patients will undergo allo-HSCT after consolidation therapy (or completion of other appropriate non-palliative strategy) according to standard procedures of the transplant center (choice of donor, conditioning regimen, GVHD and infection prophylaxis). The use of novel therapies (such as sorafenib, midaustorine, venetoclax, etc.) will be allowed as post-transplantation maintenance strategy.

Active Comparator : Best chemotherapy treatment patients will be treated according to the standard procedures of the treating center for this type of population. Patients will receive the best available treatments (including additional conventional chemotherapy or other non-palliative therapies such as 5-azacytidine, decitabine, venetoclax, midaustorine, enasidenib, etc.).

Critères d'inclusion

1. Men and women .
2. Age ≥ 65 and ≤ 75 years.
3. Newly diagnosed patients with de novo or secondary AML in first complete remission who are considered as potential candidates and eligible for an allo-HSCT procedure.
4. Presence of a donor (matched related or unrelated or haplo-mismatched) willing to donate peripheral blood stem cells.

5. Patient is fit for the allo-HSCT procedure.
6. Patient is fit for further consolidation therapy (non-transplant arm).
7. Written informed consent.

Critères de non-inclusion

1. Acute promyelocytic leukemia (AML FAB M3).
2. AML deemed not eligible for allo-HSCT.
3. Karnofsky score < 70%.
4. HIV positive patient.
5. Life expectancy less than one month according to the attending physician.
6. Acute or chronic heart failure (Cardiac ejection fraction < 40%).
7. Pulmonary function diffusion capacity < 50% predicted.
8. Estimated glomerular filtration rate < 30 ml/min (CKD-EPI).
9. Severe neurological or psychiatric disorders Recruitment procedure.

Calendrier prévisionnel

Lancement de l'étude : Décembre 2021
Fin estimée des inclusions : Janvier 2024
Nombre de patients à inclure : 172

Etablissement(s) participant(s)

> Institut Paoli-Calmettes (IPC)

(13) BOUCHES-DU-RHÔNE

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Dernière mise à jour le 08 juin 2023

< PRÉCÉDENT RETOUR AUX RÉSULTATS SUIVANT >