DECLAM - (dernière mise à jour : 24/01/2020)

http://archimaid.fr/index.php?action=show&id=1076

Informations générales

Titre de l'étude : Incidence of Neutropenic Enterocolitis Study in Acute Myeloid Leukemia Patients During Intensive Therapy

Traitement :

Type d'étude : Qualité de vie / Observationnelle

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

Schéma : Brief Summary
Neutropenia after induction or consolidation therapy for acute myeloid leukemia (AML) patients is associated with a high morbi-mortality rates, especially due to infectious complications. These are managed according to international recommandations (ECIL and IDSA) with antibiotherapy and antifungal strategy. Although the patients suffer of digestive symptoms, intestinale complications are really less explored. Neutropenic enterocolitis (NE), cytomegalovirus (CMV) colitis, Clostridium difficile colitis, specific lesion, ischemic colitis are not well-known. No prospective study evaluate NE and these digestive complications which have high morbi-mortality rates

Detailed Description
This is the first prospective study on digestive affections in an homogeneous cohort of hematological patients. These affections are unknown in neutropenic patients with digestive symptoms after induction or consolidation courses pour AML although causing high morbi-mortality rates (infections, denutrition, loss of autonomy…).
The aim of the study is to evaluate incidence of NE by clinical signs and with a systematic CT scan performed at day 5 of fever during aplastic period. An early diagnostic could decrease complications and evaluate gravity criteria which could imply surgery therapy.
The physician will performe a CTscan with injection during the induction and/or every consolidation, at the same time as the thoracic CTscan (to research an invasive fungal bronchopulmonary infection), in front of a febrile neutropenia with persistent fever after 5 days of antibiotics and presence of digestive signs.
The clinical, microbiological, radiological symptoms will be registered at every time of febrile neutropenia with digestive symptoms at induction and each consolidation courses. The patient will be get out of the study when the AML is refractory, hematopoietic stem cell transplantation is required or if whenever he want. The last visit will be at the end of consolidation courses.

Spécialités / Localisations

Spécialité n°1 : Tissus lymphoïde, hématopoïétique et apparentés

CIM10 - Localisation n°1 : **C92** - Leucémie myéloïde

Critères

Critères d'inclusion : Age > 18 years
inclusion criteria:
Every patient of hematology:
- Able to receive an intensive treatment for AML (induction then intensive consolidations) causing a neutropenia with high infectious risk
- In state to give its consent

- Affiliated to a social security system

Critères de non-inclusion : The minor patients
The patients affected by AML not being able to receive an intensive therapy
The patients affected by acute promyelocytic leukaemia
The pregnant women
The patients with HIV, hepatitis B or C
The patients under guardianship or guardianship or deprived of freedom by a court or administrative order (according to articles L1121-6 and L1121-8 of the Public health code)

Informations promoteur

Nom du promoteur : CHU Amiens-Picardie

Type de promoteur : Institutionnel

Adresse : CHU Amiens-Picardie - 80000 AMIENS

Coordonnateur : Delphine LEBON - *Mail :* lebon.delphine@chu-amiens.fr - *Tél :* +33 3 22 45 59 17

Informations centre investigateur n°1

Nom du centre : Centre Henri Becquerel

Adresse : Rue d'Amiens CS 11516 76000 ROUEN

Investigateur : Emile LEMASLE

TEC / ARC / IDE : Sandrine VAUDAUX - *Mail :* sandrine.vaudaux@chb.unicancer.fr - *Tél :* 02.32.08.24.96

Statut de l'essai : OUVERT

Liens utiles

Clinicaltrials : https://clinicaltrials.gov/ct2/show/NCT03450512