PREVENE FILOCLL10 - (dernière mise à jour : 28/01/2020)

http://archimaid.fr/index.php?action=show&id=606

Informations générales

Titre de l'étude : Preemptive therapy with Venetoclax for high risk stage A Chronic Lymphoid Leukemia patients, a phase II trial of the FILO group. PREVENE (PREemptive VENEtoclax) trial.

Traitement :

Type d'étude : Hors ciblage moléculaire

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

Schéma : Study design:
Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Drug: Venetoclax is administered according to the usual schedule an escalating dose from 20 milligram per day the first week, then 50 milligram per day the second week, 100 milligram per day the third week, 200 milligram per day the fourth week and then 400 milligram per day.
- For patient achieving a Compete Response with Minimal Residual Disease inferior to 0,01 percent in bone marrow at month 12, treatment will be stopped at month18 (18 months for total duration of treatment).
- For responding patients at month12 (Complete Response or Partial Response) with bone marrow Minimal Residual Disease inferior to 0.01 percent, treatment will be continued until month 24 (24 months for total duration of treatment).

Primary outcome:
Complete response rate (Time Frame: 12 months), according to International Workshop Chronic Lymphoid Leukemia 2008 guidelines and with Minimal Residual Disease inferior to 0.01 percent (as determined by 8-color technique) in bone marrow at month 12.

Spécialités / Localisations

Spécialité n°1 : Tissus lymphoïde, hématopoïétique et apparentés

CIM10 - Localisation n°1 : **C91** - Leucémie lymphoïde

Critères

Critères d'inclusion : - Established diagnosis of Chronic Lymphoid Leukemia by International Workshop Chronic Lymphoid Leukemia 2008 criteria with Matutes score Superior to 3, or Matutes score egal to 3 with CD200 positive and CD20 low
- High risk Binet stage A, patients presenting at least 2 from 3 risk factors: Lymphocytosis Superior to 13 Giga per liter, CD38 positive, beta2 microglobulin Superior to 2.5 milligram per liter.
Only patients with unmutated status will be treated and followed according to the trial.
- No prior chemotherapy, radiation or antibody treatment
- Age Superior to 18 years
- Life expectancy Superior to 6 months
- Performance status 0 to 2
- All parameters for risk stratification present

- Possibility of follow-up
- Adequate hepatic function per local laboratory reference range as follows: Aspartate transaminase and alanine transaminase Superior to 3.0 of upper limit of normal and Bilirubin inferior or egal to 1.5 of upper limit of normal (unless bilirubin rise is due to Gilbert's syndrome or of non-hepatic origin).
- Willingness to accept highly effective methods of contraception for the duration of therapy and 12 months thereafter
- Women of childbearing potential must have a negative serum (beta-human chorionic gonadotropin) or urine pregnancy test at Screening.
- Sign (or their legally-acceptable representatives must sign) an informed consent document indicating that they understand the purpose of and procedures required for the study, including biomarkers, and are willing to participate in the study

Critères de non-inclusion : - Binet Stage A patients with progressive disease according to International Workshop Chronic Lymphoid Leukemia 2008 criteria
- Clinically apparent autoimmune cytopenia, in particular antiglobulin test positive hemolytic anemia (positive antiglobulin test without anemia is not an exclusion criteria)
- Active secondary malignancy or chemotherapy/radiotherapy for any neoplastic disease other than Chronic Lymphoid Leukemia prior to the study
- Medical condition requiring the long term (estimated to be more than one month) use of oral corticosteroids
- Patient refusal to perform the bone marrow biopsy for evaluation points
- Patients with active bacterial, viral or fungal infection
- Subject is known to be positive for Human Immunodeficiency Virus
- Evidence of other clinically significant uncontrolled conditions
- Treatment with any other investigational agent or participating in another trial within 30 days prior to entering this study
- A female patient who is pregnant or breast feeding
- Concurrent severe diseases which exclude the administration of therapy
- Richter's syndrome
- Treatment with any of the following within 7 days prior to the first dose of study drug: Steroid therapy for anti-neoplastic intent, moderate or strong cytochrome P450 3A inhibitors, moderate or strong cytochrome P450 3A inducers
- Administration or consumption of any of the following within 3 days prior to the first dose of study drug: grapefruit or grapefruit products, Seville oranges, star fruit.
- Prior and concomitant therapy
- Malabsorption syndrome or other condition that precludes enteral route of administration
- Received a live viral vaccination within 6 months prior to the first dose of study drug. A significant history of renal, neurologic, psychiatric, endocrine, metabolic, immunologic, cardiovascular, or hepatic disease that, in the opinion of the investigator, would adversely affect the patient's participation in this study or interpretation of study outcomes
- Major surgery within 30 days prior to the first dose of study treatment
- History of prior other malignancy that could affect compliance with the protocol or interpretation of results
- Not affiliated to social security

Informations promoteur

Nom du promoteur : French Innovative Leukemia Organisation

Type de promoteur : Institutionnel

Adresse : CHU BRETONNEAU Centre Henry Kaplan Hématologie Cellulaire 2, Boulevard Tonnelé - 37000 TOURS

Coordonnateur : Docteur Vincent LEVY - *Mail : - Tél :*

Informations centre investigateur n°1

Nom du centre : Centre Hospitalier Universitaire de Lille

Adresse : 2 Avenue Oscar Lambret 59000 LILLE

Investigateur : Professeur Franck MORSCHHAUSER

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/NCT03766763?term=PREVENE&rank=1