CLavSyn - (dernière mise à jour : 19/09/2019)

ARCHIMAIDindex.php?action=show&id=363

Informations générales

Titre de l'étude : Intensification de la chimiothérapie chez les patients présentant un cancer colorectal métastatique avec des taux élevés de Lactate déshydrogénase et de Syndécan-1

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : II **Stade** : Métastasique **Ligne(s)** : 1

Schéma : In first-line metastatic colorectal cancer (mCRC), baseline prognostic factors allowing death risk and strategy stratification are lacking. In this setting, a simple biological scoring system have recently been proposed, including LDH and CD138 binary status seric values, identifying one third of patients with worst prognostic.
Intensified-chemotherapy strategies, combining 5-fluorouracile, Oxaliplatin, Irinotecan and Bevacizumab, are beneficial for patients having a bad prognostic, defined by the BRAFV600E mutation, concerning 5-8% of first line mCRC.
For the 30% of patients with LDH-CD138 elevated score, the purpose of CLavSyn phase II study is to compare the PFS of one intensified arm (FOLFOXIRI Bevacizumab) to one standard chemotherapy arm, in order to better discriminate treatment strategies, at metastatic diagnosis.

Study Arms :

- Experimental: Arm A : FOLFOXIRI - bevacizumab
FOLFOXIRI + bevacizumab, 12 cures following by maintenance chemotherapy (bevacizumab + LV5FU2 or bevacizumab-capecitabine) until disease progression or limiting toxicities

- Active Comparator: Arm B: FOLFOX or FOLFIRI - bevacizumab
FOLFOX or FOLFIRI + bevacizumab 12 cures following by maintenance chemotherapy (bevacizumab + LV5FU2 ou bevacizumab capecitabine) until disease progression or limiting toxicities

Spécialités / Localisations

Spécialité n°1 : Organes digestifs

CIM10 - Localisation n°1 : **C18** - Tumeur maligne du côlon

Spécialité n°2 : Organes digestifs

CIM10 - Localisation n°2 : **C20** - Tumeur maligne du rectum

Critères

Critères d'inclusion : - Performance status ECOG-WHO 0 or 1
- Histologically proved metastatic colorectal adenocarcinoma, with non-resectable metastases
- Adequate hematological, hepatic, and renal functions
- Signed written informed consent

Critères de non-inclusion : - Previous treatment (chemotherapy, targeted therapy, surgery) for metastatic disease
- History of autoimmune disease
- Acute infectious disease
- Known hypersensitivity grade 3-4 or contraindication to any of the study drugs
- Patient with any medical or psychiatric condition or disease which would make the patient inappropriate for entry into this study.
- Bevacizumab contraindication
- Brain metastases
- Other malignancy within the last 2 years, except for adequately treated carcinoma in situ of the cervix or squamous carcinoma of the skin, or adequately controlled limited basal cell skin cancer.
- Pregnancy, breast-feeding or absence of adequate contraception for fertile patients
- Patient under guardianship, curator or under the protection of justice.

Informations promoteur

Nom du promoteur : CHU de Besançon

Type de promoteur : Institutionnel

Adresse : - 25000 BESANCON

Coordonnateur : Docteur Marine JARY - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre Hospitalier Universitaire de Lille

Adresse : 2 Avenue Oscar Lambret 59000 LILLE

Investigateur : Docteur Anthony TURPIN

TEC / ARC / IDE : Hasna CAMARA - *Mail :* Hasna.CAMARA@CHRU-LILLE.FR - *Tél :* 03.62.94.39.51 ; TSI : 29813

Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03117972