STEREOLIVER - (dernière mise à jour : 31/07/2019)

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Informations générales

Titre de l'étude : Essai de phase II, stratifié, non randomisé, évaluant l'efficacité et la toxicité d'un traitement par radiothérapie stéréotaxique des tumeurs hépatiques primitives et secondaires.

Traitement : Métastasique ou localement avancé / Radiothérapie

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : II **Stade** : Localisé à Métastatique **Ligne(s)** : 1

Schéma : Les progrès récents en radiothérapie et en imagerie médicale ont permis l'émergence d'une nouvelle technique de radiothérapie utilisable dans le traitement des tumeurs hépatiques : la radiothérapie stéréotaxique.

L'objectif principal de cette recherche est d'estimer l'efficacité de la radiothérapie stéréotaxique chez des patients qui présentent une tumeur hépatique.

Intervention research involving the human person, phase II, prospective, multicentric, non-randomized and multi-cohort study. The eligibility criteria are broad, on purpose, so every patient, able to be treated by SBRT and unable to participate in another trial (non eligible patient or non included centers), can be included in this national study, in a prospective way.

atients will first go through an inclusion check-up consisting of:
- a clinical exam: disease history, previous treatments, weight, height, patient's performance status (ECOG) and HCC status.
- a biological test: biochemical (total bilirubin, ASAT-ALAT, LDH, albumin, alkaline phosphatases, GGT), hematological (if the patient is going to receive a fiducial), alphafoetoprotein (for HCC) and pregnancy test (if applicable)
- a tumor assessment: using a CT-scan or a MRI and using RECIST or mRECIST (if HCC), plus other morphological exams if judged useful by the investigator This check-up has to be realized within 28 days before inclusion. Then, the use of fiducial is optional.

Before the beginning of the treatment, a pre-therapeutic check-up is done:
- the inclusion check-up has to be done a second time if the treatment begins more than 28 days after the first one
- Tracking scanner.

The SBRT treatment is done in 3 to 6 times and no specific SBRT techniques are asked for, the investigator can choose according to the center habits.

After the treatment, a follow-up will be realized at 3, 6, 9, 12, 18, 24, 30 and 36 months and then once a year until the last patient included reach their 36th month of follow-up. The follow-up check-up consists of a clinical exam, biological test, tumor assessment and tolerance assessment.

Spécialités / Localisations

Spécialité n°1 : Toutes tumeurs solides

CIM10 - Localisation n°1 : **C** - Toutes localisations

Spécialité n°2 : Organes digestifs

CIM10 - Localisation n°2 : **C22** - Tumeur maligne du foie et des voies biliaires intrahépatiques

Critères

Critères d'inclusion : - Age >= 18 years old
- If fiducial use, proper hematological functions (for fiducial placement) : PT > 50% ; platelets > 50,000/L ; aPTT < twice the normal value
- With primary or secondary liver tumor and matching one of the following situations:
* Liver Metastasis (LM): anatomopathologic diagnosis of the primary tumor
* Hepatocellular Carcinoma (HCC): diagnosis achieved through biopsy or through non-invasive methods approved by AASLD criteria (Bruix, 2011)
* Cholangiocarcinoma (CC): diagnosis achieved through biopsy
- Meet the requirements for SBRT treatment:
* Liver Metastasis (LM): oligometastatic disease
* Hepatocellular Carcinoma (HCC): non eligible lesion to curative surgery
* Cholangiocarcinoma (CC): nodular lesion
- Able to receive a SBRT treatment according to the multidisciplinary consultation meeting
- Tumor evaluated by CT-scan or MRI in the 28 days prior to inclusion
- Affiliation to the National Social Security System
- With informed and signed consent

Critères de non-inclusion : - Eligibility to a curative surgery according to the multidisciplinary consultation meeting
- Contraindication to SBRT (especially Cirrhose Child C)
- Pregnant or breastfeeding women
- Patient Under guardianship or tutorship
- Impossibility to submit at the study procedures due to geographic, social or mental reasons

Informations promoteur

Nom du promoteur : Centre Oscar Lambret

Type de promoteur : Institutionnel

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Coordonnateur : - *Mail :* - *Tél :*

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03408665

Centre Oscar Lambret : https://www.centreoscarlambret.fr/recherche-cancerologique/essais-cliniques/protocole-stereoliver