2017-01 - (dernière mise à jour : 17/07/2019)

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Informations générales

Titre de l'étude : Blood Sample Collection to Evaluate Biomarkers for Hepatocellular Carcinoma

Traitement :

Type d'étude : Qualité de vie / Observationnelle

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

Schéma : Subjects with untreated Hepatocellular Carcinoma (HCC) and subjects undergoing HCC surveillance will be enrolled and have blood samples collected. Subjects undergoing HCC surveillance will be followed for 6 months and another blood sample collected at the 6 month time point.

Spécialités / Localisations

Spécialité n°1 : Organes digestifs

CIM10 - Localisation n°1 : **C22** - Tumeur maligne du foie et des voies biliaires intrahépatiques

Critères

Critères d'inclusion : All Subjects:
1- Subject is 18 years of age or older
2- Subject understands the study procedures and is able to provide informed consent to participate in the study and authorization for release of data, including personal health data, to the study investigator and sponsor

HCC Subjects:
1- Subject has a recent (within 6 months of enrollment) untreated clinically diagnosed hepatocellular carcinoma as defined by >=1 cm lesion exhibiting arterial phase hyperenhancement in combination with washout appearance and/or capsule by 4 phase CT scan or multiphase contrast enhanced MRI or biopsy is positive for HCC.

Control Subjects:
1- Non-cancer subject undergoing routine imaging surveillance for HCC
2- Definitive lack of HCC within 3 months prior to enrollment as defined by negative imaging, for HCC.
- Control Group 1 - negative by ultrasound
- Control Group 2 - negative by CT or MRI

Critères de non-inclusion : 1- Known cancer diagnosis within the past 5 years (with the exceptions of basal cell or squamous cell skin cancers).
2- Chemotherapy and/or radiation therapy within 5 years prior to enrollment/sample collection.
3- Prior or current treatment with sorafenib, regorafenib, or other treatment indicated for HCC.
4- Any HCC treatment prior to enrollment/blood sample collection (e.g., surgery, ablation, embolization, pharmacotherapy, radiotherapy, liver transplant or other treatment indicated for HCC).
5- IV contrast (e.g. CT and MRI) within 1 day [or 24 hours] of blood collection.
6- Less than 3 days between fine needle aspiration (FNA) of target pathology and blood collection.

7- Less than 7 days between biopsy (other than FNA) of target pathology and blood collection.
8- Individual has a condition the Investigator believes would interfere with his or her ability to provide informed consent, comply with the study protocol, which might confound the interpretation of the study results or put the person at undue risk.

Informations promoteur

Nom du promoteur : Exact Sciences Corporation

Type de promoteur : Industriel

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Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

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Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03628651