FOCALE - (dernière mise à jour : 24/06/2019)

http://archimaid.fr/index.php?action=show&id=470

Informations générales

Titre de l'étude : Phase 2, Multicenter, Prospective Cohort Study, Estimating the Efficacy of Focused HIFU Therapy in Patients With Localized Intermediate Risk Prostate Cancer

Traitement :

Type d'étude : Hors ciblage moléculaire

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

Schéma : The aim of the focal treatment HIFU is to destroy the cancer without causing side effects in contrast to radical treatments. Radical treatments (surgery or radiation therapy) are the standard therapies for patient with intermediate risk localized prostate cancer and good life expectancy (prostatectomy if life expectancy10 years) By destroying only the part of the gland that harbors cancer, it may indeed be possible to provide efficient cure of the disease while minimizing treatment-induced morbidity (incontinence and loss of potency). Around 20% of patients presented with a unilateral tumor: this patients are currently treated radically. No study published papers reported outcomes of a large population (>100) with intermediate risk cancers treated with Focal-HIFU (conducted with the Focal One® device). Focal therapy must be only offer within clinical trial setting (EAU (European Association of Urology) Guidelines). The aim of this cohort will be to determine the success rate of Focal-HIFU in this intermediate risk population. The result the study will be used for calculation the arms of a future random study.

170 patients with prostate cancer of intermediate risk receive the immediate treatment with focal HIFU. The treatment area will be defined using MRI data and 3D biopsies. A safety distance of at least 9 mm will be defined around the tumor. An intraoperative contrast echocardiographic control will be performed to evaluate the necrotic area. If necessary, additional HIFU lesions will be performed during the same session. In case of residual tumor demonstrated during control biopsies, additional treatment of this tumor with focal HIFU may be proposed. Patients will also have PSA (Prostate-Specific Antigen) dosage, MRI (Magnetic Resonance Imaging) exam, questionnaires and prostatic biopsies during their follow up. If the patient decides to participate in the ancillary study, a blood test (for immunological analyzes and detection of CTC (circulating tumor cells)) and a urine test (for PCA3 (The prostate cancer antigen 3 gene) test) will be performed during their follow up.

Spécialités / Localisations

Spécialité n°1 : Organes génitaux masculins

CIM10 - Localisation n°1 : **C61** - Tumeur maligne de la prostate

Critères

Critères d'inclusion : - Patient having been clearly informed of the study and having accepted, with sufficient reflection time, to participate by signing the informed consent form of the study.

- Age between 50 and 80 years with a life expectancy of more than 5 years. Patients between the ages of 75 and 80 will need to have a lower G8 score.

- Initial diagnosis of localized prostate cancer (T1 or T2a) with the following characteristics:
A multiparametric MRI showing a single invasive tumor focus at most two contiguous sextants confirmed by biopsies (index

tumor). Patients with multiple suspected MRI foci may be included if only one of these foci is confirmed by targeted biopsies.
The tumor volume on MRI should be> 0.5 cc, ie a tumor >=10 mm in its longest dimension.
Gleason score= 7 (3+4).

- PSA <= 15ng / ml.

- Patient affiliated with health insurance or beneficiary of an equivalent plan.

Critères de non-inclusion : - Contraindications to treatment with HIFU-F:
Tumor not accessible (impossibility to apply a safety margin of 9 mm around the MRI target).
Multiple intra prostatic calcifications inducing, on ultrasound, a shadow cone in the prostate preventing the penetration of ultrasound and thus the realization of the treatment.
History of pelvic irradiation
Presence of an implant (stent, catheter) located less than 1 cm from the treatment area.
Fistula of the urinary tract or rectum.
Anal or rectal fibrosis, anal or rectal stenosis or other abnormalities making it difficult to insert the Focal One® probe.
Anatomical abnormality of the rectum or rectal mucosa.
Patient with artificial sphincter, penile prosthesis or intra prostatic implant, eg stent.
History of intestinal inflammatory pathology.
Uro-genital infection in progress (the infection to be treated before HIFU treatment).
Anterior surgery at the level of the anus or rectum making the introduction of the probe impossible.
Allergy to latex.
Thickness of the rectal wall> 10mm.

- Patient undergoing treatment for benign prostatic hyperplasia (BPH) with IPSS> 25.

- Patient with a medical contraindication to Sonovue® injection.

- Patient with a medical contraindication on MRI.

- Patient already treated for prostate cancer (hormone therapy, radiotherapy, surgery).

- History of uncontrolled cancer and / or treated for less than 5 years (with the exception of basal cell skin cancer).

- History of pelvic radiotherapy.

- History of sclerosis of the bladder neck or urethral stenosis.

- Patient at risk of bleeding according to medical advice.

- Patients with unstable neurological pathology.

- Patient who has been treated for a therapeutic trial within 30 days of enrollment or who wishes to participate in an ongoing study that may interfere with this study.

- Legal person protected by law.

- Patient not able to understand the objectives of the study or refusing to comply with postoperative instructions.

Informations promoteur

Nom du promoteur : HOSPICES civils de Lyon

Type de promoteur : Institutionnel

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Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03568188