Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Confirmatory, Prospective, Open-label, Multi-centre Phase 3 Study to Evaluate Diagnostic Performance of Zirconium-labelled Girentuximab to Non-invasively Detect ccRCC by PET/CT Imaging in Patients With Indeterminate Renal Masses
Protocole ID	ZIRCON (89ZR-TLX250)
ClinicalTrials.gov ID	NCT03849118
Type(s) de cancer	Rein
Phase	Phase III
Type étude	Diagnostic
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Gad Abikhzer
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Statut	Actif en recrutement
Date d'activation	07-12-2020
But étude	This is a confirmatory, prospective, open-label, multi-centre phase 3 study to evaluate sensitivity and specificity of 89Zr-TLX250 Positron Emission Tomography/Computed Tomography (PET/CT) imaging to non-invasively detect clear cell renal cell cancer (ccRCC) in adult patients with indeterminate renal masses (IRM), scheduled for partial or total nephrectomy.Patients, will be recruited in 12-15 renal cancer care specialist centres, who have access to state-of-the-art PET/CT imaging equipment. The study involves a single administration of 89Zr-TLX250. Imaging will then be conducted 5 +/-2 days post administration. The partial/total nephrectomy will then be performed at institutional discretion any time following the PET/CT imaging visit, but no later than 90 days post administration of 89Zr-TLX250. Histological tumour samples will be prepared and used for histological diagnosis of the renal mass (ccRCC or non-ccRCC) read by a central laboratory.On Day 5 +/-2 post study drug administration, an abdominal PET/CT imaging will be obtained. In patients, in which unexpected evidence for disseminated disease is observed, PET/CT imaging may be extended to complete whole body imaging(vertex of skull to toe) at the discretion of the investigatorImage data analyses will be performed by a central image core lab. Qualitative visual analysis (presence or absence of localised 89Zr-TLX250 uptake inside or in vicinity of renal lesion, as seen on contrast-enhanced CT or MRI), will be used to assess test performance or 89Zr-TLX-250 PET/CT imaging to non-invasively detect ccRCC, using histological results from the central histological reference laboratory as standard of truth.
Critères d'éligibilité	• Written and voluntarily given Informed Consent • Male or female ≥18 years of age • Imaging evidence of a single indeterminate renal mass of ≤7cm in largest diameter (tumour stage cT1) , on CT or MRI with and without contrast agent, suspicious for ccRCC • Scheduled for lesion resection as part of regular diagnostic work-up within 90 days from planned 89Zr-TLX250 administration • Negative serum pregnancy tests in female patients of childbearing potential (at Screening and within 24 hours prior to receiving investigational product) • for patients included in France only, verification and confirmation of their affiliation with a social security • Sufficient life expectancy to justify nephrectomy • Consent to practice double-barrier contraception until a minimum of 42 days after 89Zr-TLX250 administration

Critères d'exclusion	• Bioptic procedure (rather than a partial or total nephrectomy) planned for histological species delineation of IRM • Renal mass known to be a metastasis of another primary tumour • Active non-renal malignancy requiring therapy during the time frame of the study participation • Chemotherapy, radiotherapy or immunotherapy within 4 weeks prior to the planned administration of 89Zr-TLX250 or continuing adverse effects (> grade 1) from such therapy (Common Terminology Criteria for Adverse Events (CTCAE, Version 5.0) • Planned antineoplastic therapies (for the period between administration of 89 Zr-TLX250 and imaging) • Exposure to murine or chimeric antibodies within the last 5 years • Previous administration of any radionuclide within 10 half-lives of the same • Serious non-malignant disease (e.g. psychiatric, infectious, autoimmune or metabolic) that may interfere with the objectives of the study or within the safety of compliance of the subjects as judged by the Investigator • Mental impairment that may compromise the ability to give Informed Consent and comply with the requirements of the study • Exposure to any experimental diagnostic or therapeutic drug within 30 days from the date of planned administration of 89Zr-TLX250 • Women who are pregnant or breastfeeding • Known hypersensitivity to Girentuximab or DFO (Desferrioxamine) • Renal insufficiency with glomerular filtration rate (GFR) ≤ 60 millilitres/min/1.73m2 • Vulnerable patients (e.g being in detention)