Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Étude de phase II portant sur le Savolitinib, un inhibiteur du CMET, chez des patients qui ont un cancer de la prostate métastatique résistant à la castration.
Protocole ID	IND.234B
ClinicalTrials.gov ID	NCT03385655
Type(s) de cancer	Prostate
Phase	Phase II
Médicament	Savolitinib
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Fred Saad
Coordonnateur	Amal Nadiri 514-890-8000 poste 26074
Statut	Actif en recrutement
But étude	To determine the effect of savolitinib on PSA decline and time to PSA progression. To determine objective response as determined by RECIST 1.1 criteria. To evaluate the safety and toxicity profile of savolitinib in mCRPC patients. Tertiary Objectives To obtain cfDNA and non-malignant DNA from peripheral blood clinically annotated with patient disease characteristics and follow-up data to identify potential predictive and prognostic factors and relationship between cfDNA results with clinical presentation.
Critères d'éligibilité	Patients must meet the following criteria in addition to the eligiblity criteria outlined in IND.234. • Men of childbearing potential must have agreed to use a highly effective contraceptive method during Study Drug treatment and for 6 months after stopping treatment and should not father a child or donate sperm during this period. • Patients with significantly abnormal liver diseases including viral/other hepatitis, current alcohol abuse or cirrhosis are not eligible. • Patients in whom strong inducers or inhibitors of CYP3A4 and strong inhibitors of CYP1A2 cannot be discontinued within 2 weeks before the first dose of savolitinib (3 weeks for St John's Wort) are not eligible.
Critères d'exclusion	