Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Étude de phase II portant sur le Darolutamide (ODM-201) pour traiter des patients qui ont un cancer de la prostate métastatique résistant à la castration et qui ont été traités.
Protocole ID	IND.234C
ClinicalTrials.gov ID	NCT03385655
Type(s) de cancer	Prostate
Phase	Phase II
Médicament	Darolutamide (ODM-201)
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 darolutamide 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 darolutamide 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. • Serum potassium within normal limits. • Prior abiraterone acetate or enzalutamide but not both. • No prior cytotoxic systemic chemotherapy in the CRPC setting.
Critères d'exclusion	