Essai Clinique

Généré le 04 mai 2025 à partir de

Titre	Detection and Monitoring of Metastasis by 18F-DCFPyL PET/CT in Subjects Starting Enzalutamide for Untreated Castration Resistant Prostate Cancer and Negative Conventional Imaging
Protocole ID	PROSTEP-002
ClinicalTrials.gov ID	NCT04655365
Type(s) de cancer	Prostate
Phase	Phase II
Stade	Résistant à la castration - métastatique
Type étude	Clinique
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
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Statut	Actif en recrutement
Date d'activation	12-10-2023
But étude	This study aimed to evaluate the diagnostic performance of 18F-DCFPyL (PyL) PET/CT in subjects presenting not previously treated for castration resistant prostate cancer and showing negative or equivocal findings per institutional standard of care conventional imaging
Critères d'éligibilité	• Histologically confirmed adenocarcinoma of the prostate per original diagnosis, with undergoing androgen deprivation therapy such as prior bilateral orchiectomy or surgical castration or LHRH-agonists/LHRH-antagonists. • Suspected recurrence of prostate cancer based on rising PSA under androgen deprivation therapy. Recurrent castration resistant prostate cancer patients is defined by a rising PSA >1 ng/mL under ADT or surgical castration and with testosterone castration levels < 1.7 nM (PCWG3 criteria). • Negative or equivocal findings for prostate cancer on conventional imaging bone scan AND 2) abdomen-pelvis CT/MRI and chest CT or FDG-PET/CT) performed as standard of care workup within 42 days of Day 1(accrual). • The subject is candidate for second line androgen axis targeted inhibitors such as enzalutamide and planned to receive it. • Life expectancy ≥6 months as determined by the investigator • Able and willing to provide signed informed consent and comply with protocol requirement • PSA doubling time less or equal to 10 months
Critères d'exclusion	• Subjects administered any high energy (>300 KeV) gamma-emitting radioisotope within 5 physical half-lives prior to study drug injection. • Receipt of investigational drug therapy for prostate cancer within 60 days of Day 1. • Subjects with any medical condition or other circumstances that, in the opinion of the investigator, compromise obtaining reliable data, achieving study objectives, or completing the study. • Contraindication to enzalutamide • Treatment with 5-α reductase inhibitors (finasteride, dutasteride) within 4 weeks of

randomization.