

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 H SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Armen Aprikian
Coordonnateur	Rodrigo Skowronski 514-934-1934 poste 36275
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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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

