Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Cytoreductive Stereotactic Hypofractionated Radiotherapy With Combination Ipilimumab/Nivolumab for Metastatic Kidney Cancer
Protocole ID	CYTOSHRINK
ClinicalTrials.gov ID	NCT04090710
Type(s) de cancer	Rein
Phase	Phase II
Stade	Métastatique
Type étude	Clinique
Médicament	SBRT + Ipilimumab/Nivolumab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Fabio Cury
Coordonnateur	Rodrigo Skowronski 514-934-1934 poste 36275
Statut	Actif en recrutement
Date d'activation	12-02-2024
But étude	This trial will evaluate the addition of cytoreductive stereotactic body radiation therapy (SBRT) to standard of care combination ipilimumab and nivolumab (I/N) versus I/N alone for the treatment of metastatic kidney cancer.
Critères d'éligibilité	• Biopsy proven renal cell carcinoma of any histology. • Imaging proven metastatic disease based on CT or MRI within 10 weeks of screening. • Intermediate/poor risk disease based on IMDC criteria (see Appendix II). • Primary kidney lesion amenable to SBRT. • Eligible for standard of care delivery of ipilimumab and nivolumab (I/N) according to approved product monograph.
Critères d'exclusion	• A maximum primary renal lesion size of 20 cm or greater. • Candidate for cytoreductive nephrectomy, unless a patient has refused cytoreductive nephrectomy (in this case, a discussion of cytoreductive nephrectomy and patient refusal must be documented). • Treatment with prior systemic therapy in the adjuvant or metastatic setting for renal cell carcinoma. • Previous abdominal radiation precluding SBRT. • Kanofsky Performance (KPS) score below 60 (see Appendix III). • History of auto-immune disorder precluding treatment with ipilimumab or nivolumab. • History of ataxia telangiectasia or other radiation sensitivity disorders. • Chronic corticosteroid use or other chronic immune suppressive therapy. (Participants are permitted the use of topical, ocular, intra-articular, intranasal, and inhalational corticosteroids (with minimal systemic absorption). Adrenal replacement steroid doses of prednisone ≤ 10 mg daily are permitted). • Use of medicinal herbal preparations (not including medical cannabis) unless prescribed by a

	treating physician. • Inability to lie flat for at least 30 minutes without moving. • Pregnant or lactating women. • Geographic inaccessibility for follow-up. • Inability to provide informed consent.