

Titre	Étude de phase III à répartition aléatoire comparant l'association nivolumab et ipilimumab à un placebo chez des participants atteints d'un adénocarcinome rénal localisé ayant subi une néphrectomie radicale ou partielle et qui présentent un risque élevé de récurrence de la maladie
Protocole ID	CA209-914
ClinicalTrials.gov ID	NCT03138512
Type(s) de cancer	Rein
Phase	Phase III
Stade	Adjuvant
Type étude	Traitement
Médicament	nivolumab et ipilimumab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Fred Saad
Coordonnateur	Amal Nadiri 514-890-8000 poste 26074
Statut	Fermé
But étude	The purpose of this study is to determine whether the combination of nivolumab and ipilimumab is safe and effective for delaying or preventing recurrence of cancer in patients who have experienced the partial or entire removal of a kidney
Critères d'éligibilité	<ul style="list-style-type: none">• Kidney tumor has been completely resected 4 to 12 weeks prior to randomization• Pathologic TNM staging meeting one of the following: pT2a, G3 or G4, N0 M0; pT2b, G any, N0 M0; pT3, G any, N0 M0; pT4, G any, N0 M0; pT any, G any, N1 M0• Post-nephrectomy tumor shows RCC with a predominantly clear cell histology, including participants with sarcomatoid features
Critères d'exclusion	<ul style="list-style-type: none">• Participants with an active known or suspected autoimmune disease• Known history of positive test for human immunodeficiency virus (HIV) or known acquired immunodeficiency syndrome (AIDS)• Any severe or serious, acute or chronic medical or psychiatric condition, or laboratory abnormality that may increase the risk associated with study participation• Participants with a condition requiring systemic treatment with corticosteroids