



Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Étude de phase III ouverte et à répartition aléatoire visant à comparer le nivolumab administré en association avec l'ipilimumab à la chimiothérapie standard chez des participants atteints d'un cancer urothélial non résécable ou métastatique n'ayant reçu aucun traitement antérieur
Protocole ID	CA209-901 (CheckMate901)
ClinicalTrials.gov ID	NCT03036098
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	nivolumab et ipilimumab vs chimiothérapie standard
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL H L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	Québec
Investigateur principal	Dr Louis Lacombe
Coordonnateur	Marilyn Savard 418-525-4444 poste 20414
Statut	Fermé
But étude	The purpose of this study is to determine whether an investigational immunotherapy nivolumab in combination with ipilimumab is more effective than standard of care chemotherapy in treating patients with previously untreated inoperable or metastatic urothelial cancer.
Critères d'éligibilité	• Metastatic or inoperable urothelial cancer • Must have at least 1 lesion with measurable disease • Must have full activity or, if limited, must be able to walk and carry out activities such as light house work or office work • No prior systemic chemotherapy treatment in the metastatic setting
Critères d'exclusion	• Patients with disease that is suitable for local therapy administered with curative intent • Patients with active brain metastases or leptomeningeal metastases • Patients with active, known or suspected autoimmune disease • Prior treatment with an anti-PD1, anti-PDL1, anti-PDL2, anti-CD137, or anti-CTLA4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways