Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude ouverte de phase II à répartition aléatoire évaluant le nivolumab en association avec l'ipilimumab et en monothérapie chez des patients présentant des tumeurs solides avancées ou métastatiques à fardeau mutationnel tumoral élevé.
Protocole ID	CA209-848
ClinicalTrials.gov ID	NCT03668119
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Nivolumab avec Ipilimumab ou Nivolumab en monothérapie
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
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Statut	Fermé
But étude	The purpose of this study is to determine whether nivolumab plus ipilimumab or nivolumab alone is effective and safe in the treatment of solid tumors with High Tumor Mutational Burden (TMB-H).
Critères d'éligibilité	• Refractory, metastatic, or unresectable TMB-H solid tumors who must have received at least one prior line of therapy including standard of care, if available • Available tumor tissue and blood for TMB testing • Participants must have measurable disease for response assessment
Critères d'exclusion	• Participants with melanoma, non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC) or hematological malignancy as primary site of disease • Participants who received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways • Treatment with any chemotherapy, radiation therapy, biologics for cancer, or investigational therapy within 28 days of first administration of study treatment