Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	A phase 2, randomized, open-label study of encorafenib and cetuximab plus pembrolizumab versus pembrolizumab alone in participants with previously untreated BRAF V600E-MUTANT, MSI H/DMMR metastatic colorectal cancer
Protocole ID	SEAMARK
ClinicalTrials.gov ID	NCT05217446
Type(s) de cancer	Colorectal
Phase	Phase II
Stade	Métastatique
Type étude	Clinique
Médicament	Encorafénib + cétuximab + pembrolizumab comparé à pembrolizumab en monothérapie
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Petr Kavan
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Statut	Fermé
But étude	The purpose of this study is to learn about the effects of three study medicines (encorafenib, cetuximab, and pembrolizumab) given together for the treatment of colorectal cancer that: • is metastatic (spread to other parts of the body); • has the condition of genetic hypermutability (tendency to mutation) or impaired DNA mismatch repair (MMR) • has a certain type of abnormal gene called "BRAF" and; • has not received prior treatment. All participants in this study will receive pembrolizumab at the study clinic as an intravenous (IV) infusion (given directly into a vein) at the study clinic.In addition, half of the participants will take encorafenib by mouth at home every day and cetuximab by IV infusion at the study clinic.The study team will monitor how each participant is doing with the study treatment during regular visits at the study clinic.
Critères d'éligibilité	• Locally confirmed microsatellite instability-high/ deficient mismatch repair (MSI-H/dMMR) stage IV colorectal carcinoma • Locally confirmed BRAF V600E mutation in tumor tissue or blood • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Have not received prior systemic regimens for metastatic disease. • Measurable disease per RECIST 1.1 • Adequate organ function

Critères d'exclusion	• Colorectal adenocarcinoma that is RAS mutant or for which RAS mutation status is unknown • Known active central nervous system metastases and/or carcinomatous meningitis; leptomeningeal disease • Immunodeficiency or active autoimmune disease requiring systemic treatment in the past 2 years • Presence of acute or chronic pancreatitis • Clinically significant cardiovascular diseases (eg, thromboembolic or cerebrovascular accident events ≤ 12 wks prior) • Received a live or live-attenuated vaccine within 30 days of planned start of study medication • Previous treatment with any selective BRAF inhibitor (eg, encorafenib, dabrafenib, vemurafenib, XL281/BMS-908662) or any epidermal growth factor receptor (EGFR) inhibitor (eg, cetuximab, panitumumab). • Previous treatment with an immune checkpoint inhibitor (eg, anti-programmed cell death [PD-1], anti-PD-L1 or anti-PD-L2 agent); or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, CTLA-4, OX 40, CD137).