

Essai Clinique Généré le 28 avr. 2024 à partir de

Titre	A Randomized, Multi-center, Double-blinded, Placebo-controlled Phase 3 Study of Nivolumab and Ipilimumab, Nivolumab Monotherapy, or Placebo in Combination With Trans-arterial ChemoEmbolization (TACE) in Patients With Intermediate-stage Hepatocellular Carcinoma (HCC)
Protocole ID	CheckMate 74W
ClinicalTrials.gov ID	NCT04340193
Type(s) de cancer	Foie
Phase	Phase III
Type étude	Clinique
Médicament	Nivolumab et Ipilimumab, Nivolumab monothérapie ou placebo en association avec TACE
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL H L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Félix Couture
Coordonnateur	Maryse Gingras 418-691-5781
Statut	Actif en recrutement
But étude	The purpose of this study is to compare effectiveness and safety of nivolumab with and without ipilimumab in combination with Trans-arterial ChemoEmbolization (TACE) to TACE alone in participants with intermediate liver cancer
Critères d'éligibilité	 Participant has intermediate-stage HCC (hepatocellular carcinoma) whose tumor characteristics exceed the BMU7 criteria and is eligible for TACE Participant has histologic confirmation of HCC Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1 Men and Women must agree to follow methods of contraception Participants are eligible to enroll if they have non-viral related HCC, or if they have HBV-HCC, or HCV-HCC
Critères d'exclusion	 Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC Prior liver transplant or participants who are on the waiting list for liver transplantation Active, known, or suspected autoimmune disease Participants with a condition requiring systemic treatment with either corticosteroids or other immunosuppressive medications Any previous TACE or TAE (trans-arterial embolization without instillation of chemotherapy agent) procedure for HCC Known or suspected allergy to nivolumab, ipilimumab, or study drug components given in association with this trial Other protocol defined inclusion/exclusion criteria could apply