Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude multicentrique de phase III, à répartition aléatoire, à double insu et contrôlée par placebo sur le durvalumab en monothérapie ou en association avec le bévacizumab comme traitement adjuvant chez des patients atteints d'un carcinome hépatocellulaire exposés à un risque élevé de récidive après une résection ou une ablation hépatique à visée curative
Protocole ID	EMERALD-2
ClinicalTrials.gov ID	NCT03847428
Type(s) de cancer	Foie
Phase	Phase III
Type étude	Traitement
Médicament	Durvalumab monothérapie ou combiné au Bevacizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Maxime Chénard-Poirier
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Statut	Fermé
But étude	This is a Phase III, randomized, double-blind, placebo-controlled, multi-center, global study to assess the efficacy and safety of durvalumab in combination with bevacizumab or durvalumab monotherapy or placebo as adjuvant therapy. This study will be conducted in patients with HCC who are at high risk of recurrence after curative hepatic resection or ablation.
Critères d'éligibilité	• Histologically or cytologically, newly diagnosed, confirmed HCC and successfully completed curative therapy (resection or ablation) • Imaging to confirm disease-free status within 28 days prior to randomization • ECOG 0-1 at enrolment • Child-Pugh score of 5 or 6 • Adequate organ and marrow function
Critères d'exclusion	• Known fibrolamellar HCC, sarcomatoid HCC or mixed cholangiocarcinoma and HCC • Evidence of metastasis, macrovascular invasion or co-existing malignant disease on baseline imaging • History of hepatic encephalopathy within 12 months prior to randomization • Evidence, by Investigator assessment, of varices at risk of bleeding on upper endoscopy or contrast-enhanced cross-sectional imaging • Patients with Vp1 to Vp4 portal vein thrombosis on baseline imaging are excluded • Active co-infection with both HBV and HCV, or co-infected with HBV and hepatitis D virus • Receipt of prior systemic anticancer therapy for HCC • Those on a waiting list for liver transplantation