Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude multicentrique de phase III, à répartition aléatoire, à double insu et contrôlée par placebo visant à évaluer la chimio-embolisation transartérielle (CETA) combinée à une monothérapie par le durvalumab ou à un traitement d'association par le durvalumab et le bévacizumab chez des patients atteints d'un carcinome hépatocellulaire locorégional
Protocole ID	EMERALD-1
ClinicalTrials.gov ID	NCT03778957
Type(s) de cancer	Foie
Phase	Phase III
Type étude	Traitement
Médicament	Chimioembolisation transartérielle avec durvalumab seul ou en association avec le bévacizumab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Hélène Castel
Coordonnateur	Joannie Blanchette 514-890-8000 poste 36304
Statut	Actif en recrutement
But étude	This is a randomized, double-blind, placebo-controlled, multicenter, global Phase III study to determine the efficacy and safety of transarterial chemoembolization (TACE) treatment in combination with durvalumab monotherapy or TACE given with durvalumab plus bevacizumab therapy compared to TACE therapy alone in patients with locoregional hepatocellular carcinoma not amenable to curative therapy
Critères d'éligibilité	• No evidence of extrahepatic disease • Disease not amenable to curative surgery or transplantation or curative ablation but disease amenable to TACE • Child-Pugh score class A to B7 and Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at enrollment • Measurable disease by Modified Response Criteria in Solid Tumors (mRECIST) criteria • Adequate organ and marrow function
Critères d'exclusion	• Any history of nephrotic or nephritic syndrome • Clinically significant cardiovascular disease or history of arterioembolic event including a stroke or myocardial infarction • Any prior or current evidence of coagulopathy or bleeding diathesis or patients who had any kind of surgery in the past 28 days (biopsies are exempt from this exclusion) • History of abdominal fistula or GI perforation, non healed gastric ulcer that is refractory to treatment, or active GI bleeding within 6 months prior to enrollment • Patients with Vp3 and Vp4 portal vein thrombosis on baseline imaging are excluded