Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Le rôle des traitements multimodaux chez les patients stratifiés selon le risque atteints de cancer colorectal avec métastases limitées au poumon
Protocole ID	CT0078A
ClinicalTrials.gov ID	NCT03599752
Type(s) de cancer	Côlon et rectum
Phase	Phase II
Stade	Métastatique
Type étude	Traitement
Médicament	Chimiothérapie et métastasectomie pulmonaire
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Moishe Liberman
Coordonnateur	Adeline Jouquan 514-890-8000 poste 26214
Statut	Fermé
But étude	This phase II trial studies how well chemotherapy and/or metastasectomy work in treating patients with colorectal adenocarcinoma that has spread to the lungs (metastases). Drugs used in chemotherapy work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Metastasectomy is a surgical procedure that removes tumors formed from cells that have spread from other places in the body. It is not yet known if chemotherapy and metastasectomy together works better in treating patients with metastatic colorectal adenocarcinoma with lung metastases.
Critères d'éligibilité	• Histological confirmation of colorectal adenocarcinoma • Metastatic colorectal cancer involving the lung classified as determined by the treating clinical team • Diagnosis of colorectal metastasis to lung made either histologically with trans-thoracic needle biopsy or clinically based on radiographic imaging • Identification as a medically appropriate candidate for surgical resection of the lung metastasis (metastases) according to the evaluating cardiothoracic surgeon. Standard justification for deeming a patient medically operable based on: • Pulmonary reserve adequate to tolerate complete resection of all intrathoracic disease, as deemed by thoracic surgeon, which may be determined by: • Baseline forced expiratory volume in one second (FEV1) > 40% predicted • Post-operative predicted FEV1 > 30% predicted • Diffusion capacity of the lung for carbon monoxide (DLCO) > 40% predicted • Absent baseline hypoxemia and/or hypercapnia • Exercise oxygen consumption > 50% predicted • Absent severe pulmonary hypertension • Absent severe cerebral, cardiac, or peripheral vascular disease • Absent severe chronic heart disease • Ability to tolerate surgical resection and acceptable operative risk as deemed by thoracic surgeon based on performance status and medical comorbidities • Identification as a medically appropriate candidate for systemic chemotherapy at the discretion of the evaluating medical oncologist • Resection/definitive therapy of primary colorectal tumor with no suspicion of recurrence. Prior

	radiation to a rectal adenocarcinoma is permitted • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Ability to provide informed consent for participation • Leukocytes >= 2,000/mcL • Absolute neutrophil count >= 1,000/mcL • Hemoglobin >= 9.0 gm/dL • Platelet count >= 100,000/mcL • Total bilirubin =< 1.5 x institutional upper limit of normal (ULN) (except patients with Gilbert Syndrome, who can have total bilirubin < 3.0 mg/dL) • Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase [SGPT]) =< 2.5 x ULN • Serum creatinine =< 1.5 x ULN OR creatinine clearance (CrCl >= 50 mL/min (if using the Cockcroft-Gault formula) • Patients (men and women) of child bearing potential should use an effective (for them) method of birth control throughout their participation in this study
Critères d'exclusion	• Tumor involvement at other metastatic sites (e.g., liver, distant lymph nodes) that has not been definitively treated. Prior surgical resection for metastatic disease at other (non-pulmonary) sites is permitted • Presence of intact primary colorectal adenocarcinoma (or of an anastomotic recurrence) • Previous radiotherapy to a lung metastasis that is still detectable radiographically • Known dihydropyrimidine dehydrogenase (DPD) deficiency that would preclude the patient from tolerating 5- fluorouracil chemotherapy • Prior intolerance of systemic therapies used as standard regimens in the treatment of metastatic CRC that would prohibit further receipt of systemic chemotherapy and/or biologic agents -e.g.,5-fluorouracil, oxaliplatin, irinotecan, anti-VEGF therapies (e.g., bevacizumab, ramucirumab), or anti-EGFR therapies (e.g., cetuximab, panitumumab, for patients with RAS wild-type colorectal tumors) • Prior therapy with regorafenib or trifluridine/tipiracil (TAS-102) for metastatic/unresectable colorectal cancer • Synchronous primary or prior malignancy in the past 5 years other than non-melanomatous skin cancer or in situ cancer • Pregnant or lactating women, as treatment involves unforeseeable risks to the embryo or fetus