Essai Clinique

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Titre	Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients With Stage IIA Colon Cancer
Protocole ID	CRC.9 (COBRA)
ClinicalTrials.gov ID	NCT04068103
Type(s) de cancer	Colorectal
Phase	Phase II-III
Type étude	Clinique
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
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Statut	Fermé
But étude	This phase II/III trial studies how well circulating tumor deoxyribonucleic acid (ctDNA) testing in the blood works in predicting treatment for patients with stage IIA colon cancer after surgery. ctDNA are circulating tumor cells that are shed by tumors into the blood. Finding ctDNA in the blood means that there is very likely some small amounts of cancer that remain after surgery. However, this cancer, if detected, cannot be found on other tests usually used to find cancer, as it is too small. Testing for ctDNA levels may help identify patients with colon cancer after surgery who do benefit, and those who do not benefit, from receiving chemotherapy.
Critères d'éligibilité	• The patient must have signed and dated an Institutional Review Board (IRB)-approved consent form that conforms to federal and institutional guidelines. • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. • Histologically/pathologically confirmed stage IIA adenocarcinoma of the colon (T3, N0, M0) with at least 12 lymph nodes examined at the time of surgical resection. • Appropriate for active surveillance (i.e., no adjuvant chemotherapy) at the discretion of and as documented by the evaluating oncologist based on current practice patterns. • The distal extent of the tumor must be >= 12 cm from the anal verge on pre-surgical endoscopy (i.e., excluding rectal adenocarcinomas warranting treatment with chemoradiation). If the patient did not undergo a pre-surgical endoscopy, then the distal extent of the tumor must be >= 12 cm from the anal verge as determined by surgical examination or pre-operative imaging. • The patient must have had an en bloc complete gross resection of tumor (curative resection) as definitive surgical cancer treatment within 14 to 60 days of study randomization. Patients who have had a two-stage surgical procedure to first provide a decompressive colostomy and then, in a later procedure, to have the definitive surgical resection, are eligible. • Availability and provision of adequate surgical tumor tissue for molecular diagnostics and confirmatory profiling. • Absolute neutrophil count (ANC) must be >= 1200/mm^3 (within 28 days before randomization). • Platelet count must be >= 100,000/mm^3 (within 28 days before randomization); and • Hemoglobin must be >= 9 g/dL (within 28 days before randomization). • Total bilirubin must be =< ULN (upper limit of normal) for the lab (within 28 days before randomization) unless the patient has a chronic grade 1 bilirubin elevation due to Gilbert?s disease or similar syndrome involving slow conjugation of bilirubin; and • Alkaline phosphatase must be < 2.5 x ULN for the lab (within 28 days before randomization); and • Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) must be < 1.5 x ULN for the lab (within 28 days before randomization). • Serum creatinine =< 1.5 x ULN for the lab or measured or calculated creatinine clearance >=

	50 mL/min using the Cockcroft-Gault formula for patients with creatinine levels > 1.5 x ULN for the lab (within 28 days before randomization). • Pregnancy test (urine or serum according to institutional standard) done within 14 days before randomization must be negative (for women of childbearing potential only). • Patients receiving a coumarin-derivative anticoagulant must agree to weekly monitoring of international normalized ratio (INR) if they are randomized to Arm 2 and receive capecitabine.

Critères d'exclusion	• Colon cancer histology other than adenocarcinoma (i.e., neuroendocrine carcinoma, sarcoma, lymphoma, squamous cell carcinoma, etc.).
	• Pathologic, clinical, or radiologic evidence of metastatic disease. This includes isolated, distant, or non-contiguous intra-abdominal metastases, even if resected (including the presence of satellite nodules constituting N1c disease in the absence of lymph node involvement).
	• Tumor-related bowel perforation.
	• History of prior invasive colon malignancy, regardless of disease-free interval.
	• History of organ transplantation.
	• Any prior systemic chemotherapy, targeted therapy, or immunotherapy; or radiation therapy administered as treatment for colorectal cancer (e.g., primary rectal adenocarcinomas for which treatment with neoadjuvant chemoradiation is warranted are not permitted).
	• Other invasive malignancy within 5 years before randomization. Exceptions are colonic polyps, non-melanoma skin cancer or carcinoma-in-situ of the cervix.
	• Synchronous primary rectal and/or colon cancers.
	• Antineoplastic therapy (e.g., chemotherapy, targeted therapy, or immunotherapy) within 5 years before randomization. (For the purposes of this study, hormonal therapy is not considered chemotherapy.).
	• Uncontrolled cardiac disease, in the opinion of the treating medical oncologist, that would preclude the use of any of the drugs included in the GI005 treatment regimen. This includes but is not limited to:
	  • Clinically unstable cardiac disease, including unstable atrial fibrillation, symptomatic bradycardia, unstable congestive heart failure, active myocardial ischemia, or indwelling temporary pacemaker.
	  • Ventricular tachycardia or supraventricular tachycardia that requires treatment with class Ia antiarrhythmic drugs (e.g., quinidine, procainamide, disopyramide) or class III antiarrhythmic drug (e.g., sotalol, amiodarone, dofetilide). Use of other antiarrhythmic drugs is permitted.
	  • Second- or third-degree atrioventricular (AV) block unless treated with a permanent pacemaker.
	  • Complete left bundle branch block (LBBB) unless treated with a permanent pacemaker.
	• Sensory or motor neuropathy >= grade 2, according to Common Terminology Criteria for Adverse Events (CTCAE) version (v) 5.0.
	• Active seizure disorder uncontrolled by medication.
	• Active or chronic infection requiring systemic therapy.
	• Known homozygous DPD (dihydropyrimidine dehydrogenase) deficiency.
	• Pregnancy or lactation at the time of randomization.
	• Co-morbid illnesses or other concurrent disease that, in the judgement of the clinician obtaining informed consent, would make the patient inappropriate for entry into this study (i.e., unable to tolerate 6 months of combination chemotherapy or interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens or prevent required follow-up).