Essai Clinique

Généré le 23 avr. 2024 à partir de

Titre	Essai international randomisé de phase III comparant une chimiothérapie au mFOLFIRINOX à la chimiothérapie mFOLFOX comme traitement adjuvant pour un cancer du côlon au stade III à risque élevé
Protocole ID	IROCAS / CO.27
ClinicalTrials.gov ID	NCT02967289
Type(s) de cancer	Côlon et rectum
Phase	Phase III
Type étude	Traitement
Médicament	5-fluorouracil, folinic acid, irinotecan and oxaliplatin
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dr Petr Kavan
Coordonnateur	Julia Lainer Palacios 514-340-8222 poste 23766
Statut	Fermé
Date d'activation	18-09-2017
But étude	The trial is a phase III, multicenter, open-labeled randomized trial comparing the association 5-fluorouracil, folinic acid, irinotecan and oxaliplatin (mFOLFIRINOX) versus oxaliplatin, folinic acid, 5FU (mFOLFOX 6) chemotherapy protocols in patients with high-risk stage III colon cancer in the adjuvant setting.
Critères d'éligibilité	• Patient ≥18 years and < 71years • Patient with ECOG ≤1 • Pathologically confirmed high-risk stage III colon adenocarcinoma, restricted to pT4N1 or pT1-4N2 tumor. • Curative R0 surgical resection within 42 days before randomization. • Patients who have undergone surgery for colon cancer, defined as a tumor location >12 cm from the anal verge by endoscopy and/or above the peritoneal reflection at surgery (high rectum), without gross or microscopic evidence of residual disease after surgery with curative intent • Start of study drug treatment has to be performed less than 56 days after surgery. • No prior chemotherapy. • No prior abdominal or pelvic irradiation. • Patient with adequate organ function: Absolute neutrophil count (ANC) ≥ 2 x 109/L Haemoglobin ≥9 g/dL Platelets (PTL) ≥100 x 109/L AST/ALT ≤2.5 x ULN Alkaline phosphatase ≤2.5 x ULN Total Bilirubin ≤1.5 x ULN (Upper Limit of Normal) Creatinine clearance ≥50 mL/min (Cockcroft and Gault formula) Kalemia, magnesemia, calcemia ≥ 1 LLN (Lower Limit of Normal) Carcinoembryogenic antigen (CEA) ≤10ng/mL after surgery (during screening period) • Adequate contraception if applicable. • Patient able and willing to comply with study procedures as per protocol • Patient able to understand and willing to sign and date the written voluntary informed consent form at screening visit prior to any protocol-specific procedures • Public or private health insurance coverage • Life expectancy of > or = at 5 years

Critères d'exclusion	• Major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to study treatment start. Incompletely healed wounds or anticipation of the need for major surgical procedure during the course of the study • Metastatic disease • Presence of inflammatory bowel disease and/or ileus • Known hypersensitivity reaction to any of the components of study treatments. • Pregnancy (absence to be confirmed by β-hCG test) or breast-feeding period • Clinically relevant coronary artery disease or history of myocardial infarction in the last 12 months, or high risk of uncontrolled arrhythmia (for men: QT/QTc ≥450 msec, for women: QT/QTc ≥470 msec) • Previous malignancy in the last 5 years except curative treated basal cell carcinoma of the skin and/or in situ carcinoma of the cervix • Medical, geographical, sociological, psychological or legal conditions that would not permit the patient to complete the study or sign informed consent • History or current evidence on physical examination of central nervous system disease or peripheral neuropathy ≥ grade 1 Common Toxicity Criteria for Adverse Events (CTCAE) v4.03. • Any significant disease which, in the investigator's opinion, would exclude the patient from the study. • Known DPD deficiency or UGT1A1 homozygous 7/7 • Patients already included in another therapeutic trial involving an experimental drug