Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	Essai multicentrique, à répartition aléatoire et contrôlé portant sur l'utilisation de l'héparine de faible poids moléculaire sur une période périopératoire prolongée pour améliorer les chances de survie après la résection chirurgicale d'un cancer colorectal.
Protocole ID	PERIOP-01
ClinicalTrials.gov ID	NCT01455831
Type(s) de cancer	Colorectal
Phase	Phase III
Médicament	Tinzaparin
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dre Vicky Tagalakis
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Statut	Fermé
But étude	The human body has a natural stress response to surgery, including the formation of blood clots. This response to surgery has been shown to increase metastases (the spread of cancer cells to other organs in the body). These metastases cannot be seen at the time of surgery but when they grow into new tumors, the cancer has recurred (come back). A blood thinner called "low molecular weight heparin" (LMWH) can suppress the development of metastases after surgery in animal experiments. The investigators want to see if giving patients with colon cancer the blood thinner, LMWH, around the time of surgery can decrease the chance of their cancer spreading to other organs (metastases) and coming back (recurrence). The investigators need 1075 patients to answer our scientific question. Patients who give informed consent will be randomly put into one of two groups, the experimental group and the control group. The patients in the control group will be treated with LMWH starting a few hours after surgery and every day until they leave the hospital. This is how most patients are treated after colon cancer surgery (standard care). The patients in the experimental group will be treated with LMWH for a longer period of time, starting on the day they agree to have surgery and continuing for two months after surgery. All the patients will be followed for at least three years after surgery to find out if their cancer has recurred (come back). If LMWH treatment around the time of surgery reduces the chance of recurrence in patients with colon cancer, it would improve the health and quality of life for these patients.
Critères d'éligibilité	• Diagnosis of pathologically-confirmed invasive adenocarcinoma of the colon • Pre-operative work-up that reveals potential resectability (CT scan or MRI of the abdomen and pelvis within 90 days of randomization) • Pre-operative work-up that reveals no evidence of metastatic disease (CT scan or MRI of the abdomen and pelvis and chest X-ray (CXR) or CT scan of the chest within 90 days of randomization) • A planned surgical operation for resection of the colon cancer within 6 weeks from the date of randomization • ECOG performance status 0 or 1 • Age ≥18 years • Hemoglobin ≥ 80g/L • Able and willing to sign Research Ethics Board (REB)-approved written consent form • Able and willing to comply with study procedures and follow-up examinations contained within the written consent form.

Critères d'exclusion	• Rectal adenocarcinoma (defined as tumour below the peritoneal reflection on imaging or within 15 cm of the anal verge by rigid sigmoidoscopy) • Carcinoma only present in a completely excised polyp (i.e. no residual tumour evident in the colon) • Prior VTE including deep vein thrombosis (DVT) or pulmonary embolism (PE) • Requirement for full dose peri-operative anticoagulation • Contraindication to heparin therapy • history of heparin induced thrombocytopenia (HIT) • platelet count of less than 100 x 109/L • actively bleeding • severe hypertension (SBP >200 and/or DBP >120) on more than one reading • documented peptic ulcer within 6 weeks • severe hepatic failure (INR >1.8) • creatinine clearance of < 30 ml/min as calculated by the Cockcroft-Gault formula • heparin or pork allergy • Other contraindication to anticoagulation • Geographic inaccessibility (less likely to comply with required follow-up visits and care) • Participating in another interventional trial that may result in co-intervention or contamination (to be determined by sponsor) • History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within 5 years of the colorectal cancer diagnosis • Treatment, including radiation therapy, chemotherapy or targeted therapy, administered for the currently diagnosed colon cancer prior to randomization • Pregnant or lactating • Unable/unwilling to providing informed consent.