Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Un essai de phase II/III randomisé de la chimioradiothérapie préopératoire versus la chimiothérapie préopératoire pour le traitement du cancer gastrique résécable.
Protocole ID	NCIC CTG GA.1
ClinicalTrials.gov ID	NCT01924819
Type(s) de cancer	Estomac
Phase	Autres
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Moishe Liberman
Coordonnateur	Adeline Jouquan 514-890-8000 poste 26214
Statut	Fermé
Date d'activation	10-12-2013
But étude	Gastric cancer remains a significant global public health problem. Although in developed countries its incidence has dramatically decreased, on a worldwide scale it is still a leading cause of cancer-related deaths. Surgery is the only potentially curative treatment for gastric cancer. Although the survival rates for patients with early stage disease (stage 1A and 1B) are good, this subgroup of patients constitutes only 20% of those undergoing resection. The majority of patients will have locally advanced or metastatic disease at presentation, which has an extremely poor prognosis. The current five-year survival rate for gastric cancer in Western countries is approximately 20-30%, a figure that has improved little over the past 30 years. The intervention arm in TOPGEAR consists of pre-operative chemotherapy, pre-operative chemoradiotherapy, surgery and post-operative chemotherapy. The control arm consists of pre-operative chemotherapy, surgery and post-operative chemotherapy. The primary objective of TOPGEAR is to investigate whether the addition of chemoradiotherapy to chemotherapy is superior to chemotherapy alone in the neoadjuvant setting by improving pathological complete response rates in the first instance, and subsequently overall survival, in patients undergoing adequate surgery (D1+ dissection) for resectable gastric cancer.
Critères d'éligibilité	• Histologically proven adenocarcinoma of the stomach or gastroesophageal junction (GEJ) that is: • Stage IB (T1N1 only, T2N0 not eligible) - IIIC, i.e. T3 - T4 and/or node positive, according to American Joint Committee on Cancer (AJCC) 7th edition. • Considered operable following initial staging investigations (surgeon believes that an R0 resection can be achieved) (GEJ tumours are defined as tumours that arise in the cardia or at the GEJ that do not involve more than 2cm of the lower esophagus, i.e. Siewert Type II and Siewert Type III) • Age >=18 years • Eastern Cooperative Oncology Group (ECOG) performance status 0-1 • Adequate organ function defined as follows: • Bone marrow: Haemoglobin >=90 g/L, Absolute neutrophil count (ANC) >=1.5 x 10? /L, White blood cell count >=3 x 10? /L, Platelet count >=100 x 10? /L • Hepatic: Serum bilirubin <=1.5 x upper limit of normal (ULN), aspartate aminotransferase (AST) and/or alanine transaminase (ALT) <=3.0 x ULN • Renal: Serum creatinine <=0.150 mmol/L, Calculated creatinine clearance >=50 mL/min • Disease which can be radically treated with radiotherapy to 45 Gy with standard fractionation • Any patient with a history of ischaemic heart disease and abnormal ECG, or who is over 60 years of age should have a pre-treatment evaluation of cardiac function with a multigated acquisition (MUGA) scan or echocardiogram. Patients will only be included if the left ventricular ejection fraction is >=50%. • Written informed consent obtained before randomization

	• Negative pregnancy test for women of childbearing potential within 7 days of commencing study treatment. Males and females of reproductive potential must agree to practice adequate contraceptive measures.
Critères d'exclusion	• Evidence of metastatic disease • Prior chemotherapy or radiotherapy • Patients with a past history of cancer in the 5 years before randomization except for the following. Patients with squamous or basal cell carcinoma of the skin that has been effectively treated, and patients with carcinoma in situ of the cervix that has been treated by operation only are eligible, even if they were diagnosed and treated within the 5 years before randomization. • Patients with other significant underlying medical conditions that may be aggravated by the study treatment or are not controlled • Pregnant or lactating females or female patients of childbearing potential who have not been surgically sterilized or are without adequate contraceptive measures • Cardiac failure and other contraindications to epirubicin • Patients with impaired gastrointestinal absorption for whatever reason • Patients medically unfit for cisplatin chemotherapy due to one or more of the following reasons: • Clinically significant sensorineural hearing impairment (audiometric abnormalities without corresponding clinical deafness will not be regarded as a contraindication to cisplatin) • Severe tinnitus • Renal impairment (GFR <=50ml/min) • Peripheral neuropathy >=grade 2 • Inability to tolerate intravenous hydration e.g due to cardiac disease • Co-morbidities (based on clinical judgement by the investigator) that in the view of the investigator would preclude the safe administration of cisplatin.