Essai Clinique

Généré le 29 avr. 2024 à partir de http://www.geoq.info/fr/pub/essai-clinique-3470-pdf

Titre	Apixaban for the Prevention of Venous Thromboembolism in High-Risk Ambulatory Cancer Patients: A Randomized Placebo-Controlled, Double-Blind Clinical Trial
Protocole ID	AVERT
ClinicalTrials.gov ID	NCT02048865
Type(s) de cancer	Autre
Phase	Phase II
Type étude	Support
Médicament	Apixaban
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Statut	Fermé
But étude	Cancer patients have an increased risk of developing blood clots in the veins compared to non-cancer patients. Cancer patients who develop blood clots can lead to reduced life expectancy, delayed cancer treatment, and decreased quality of life. Prevention is the most effective way to decrease the complications associated with blood clots in the veins. Although previous clinical trials have shown some benefit on the use of medication to prevent blood clots in the veins in ambulatory cancer patients, these studies have been inconclusive in demonstrating that existing blood thinners significantly reduce the rate of blood clots in cancer patients. One possible explanation relates to the fact that these studies have included a large proportion of cancer patients who are a low risk of developing blood clots in the veins. We are proposing to identify cancer patients who are at a high risk of developing blood clots by using a validated tool at the time of their cancer diagnosis. The identified high risk cancer patients will be asked to participate in a trial to test the safety and efficacy of a new oral medication that has been used to prevent blood clots in patients undergoing surgery. We are enrolling 574 patients in 7 Canadian centers (Ottawa, Halifax, Montreal, Vancouver, Sault Ste. Marie, Toronto and Hamilton). 287 patients will receive the study drug and 287 will receive an inactive substance. Analysis will be performed to assess the safety and the superiority of the study drug.
Critères d'éligibilité	• A newly diagnosed cancer site or progression of the malignant disease after complete or partial remission. • Initiating a new course of chemotherapy with a minimum intent of 3 months therapy • A VTE risk stratification score of ≥ 2, according to the scoring method • Age 18 years old or older • Provide written informed consent
Critères d'exclusion	• Lesions or conditions at increased risk of clinically significant bleeding (eg. active peptic ulcer disease) • Objectively confirmed substantial liver insufficiency as defined by clinical manifestations of ascites, cirrhosis, encephalopathy and/or jaundice and/or biochemical abnormalities in liver function tests including hypoalbuminemia (< 3.5 gr/dL), elevated levels of total bilirubin (> 25 umol/L), elevated liver transaminases (2 times the upper limit of normal) and/or biochemical diagnosis of biliary tract obstruction (elevated levels of gamma-glutamyl transferase and alkaline phosphatase, 3 times the upper limit of normal). *

- Diagnosis of basal cell or squamous cell carcinoma of the skin or acute leukemia or myelodysplastic syndrome**
- Planned stem cell transplant
- Life expectancy less than 6 months
- Acute or chronic renal insufficiency with glomerular filtration rate (GFR) < 30 ml/min calculated by the Cockroft and Gault formula.
- Pregnancy***
- Continuous anticoagulation with vitamin K antagonists, low-molecular-weight heparin (LMWH), or other oral anticoagulants
- Weight < 40 Kg
- Platelet count < 50 x 109/L
- Known allergies to ingredients contained in apixaban
- Use of any contraindicated medications with apixaban