

Titre	A Phase 2 Pilot Randomized Controlled Trial Assessing Feasibility of Thromboprophylaxis With Apixaban in JAK2-positive Myeloproliferative Neoplasm Patients
Protocole ID	AIRPORT-MPN
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT04243122">NCT04243122</a>
Type(s) de cancer	NMP : Vaquez , Thrombocythémie essentielle, Métaplasie myéloïde
Phase	Phase II
Type étude	Clinique
Médicament	Apixaban
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE  HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
Investigateur principal	Dre Dominique Toupin
Coordonnateur	Anick Champoux 819-346-1110 poste 12811
Statut	Fermé
But étude	<p>Myeloproliferative neoplasms (MPNs) are blood disorders that occur when the body makes too many white or red blood cells, or platelets. This overproduction of blood cells in the bone marrow can create problems for blood flow and lead to various symptoms. One of the major problems is the formation of blood clots. These may form in the veins of a patient's legs or arms where they cause leg or arm pain, swelling or difficulty walking. These clots may travel to the lung and then cause chest pain, shortness of breath and sometimes death. Blood clots can also lead to poor or no blood flow to one's heart, brain, or other organs, causing damages that cannot be easily or ever repaired, such as stroke or heart attack. Patients diagnosed with certain types of MPN are associated with a higher risk of developing blood clots and related complications. For this reason, MPN patients are usually treated with low-dose aspirin, a common drug used for blood clot prevention, on long-term basis to prevent the formation of blood clots and other complications. However, recent studies also show that the risk of blood clots remains elevated in MPN patients treated with aspirin, and there may not be improvement or reduction in fatal or other events that are associated with blood clots. In addition, since this medical condition is rare, so there's a lack of studies done with high quality results to help physicians decide the best treatment plan for these patients.</p> <p>This study drug, apixaban, is a new type of orally-taken blood thinner that has been shown to be effective and safe for prevention and treatment of blood clots in various patient populations. The investigators will evaluate whether apixaban is safer and/or better at preventing blood clots and other complications in MPN patients compared to aspirin.</p>
Critères d'éligibilité	<ul style="list-style-type: none"><li>• Male or female subjects aged 18 years or older,</li><li>• Confirmed diagnosis of PV, JAK2ET or JAK2 pre-fibrotic MF, per local clinical definitions</li><li>• Able and willing to comply with study procedures and follow-up examinations contained within the written consent form</li></ul>
Critères d'exclusion	<ul style="list-style-type: none"><li>• Known allergy to apixaban or aspirin,</li><li>• Another need for anticoagulation or specific anti-platelet therapy,</li><li>• Contraindication to thromboprophylaxis (which would specifically include but not be limited to platelets less than <math>50 \times 10^9/L</math> and acquired Von Willebrand disease),</li><li>• Current pregnancy or breast-feeding,</li><li>• Renal dysfunction (Creatine Clearance <math>&lt;25 \text{ mL/min}</math>),</li><li>• Known liver disease</li></ul>

- Currently on any medication with a known interaction to apixaban
- Unwilling to use an effective means of contraception for women of childbearing potential
- Overtly fibrotic myelofibrosis
- Myelodysplastic/myeloproliferative neoplasms