Essai Clinique

Généré le 28 mars 2024 à partir de

Titre	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study Of Navitoclax In Combination With Ruxolitinib Versus Ruxolitinib In Subjects With Myelofibrosis
Protocole ID	M16-191 (TRANSFORM-1)
ClinicalTrials.gov ID	NCT04472598
Type(s) de cancer	NMP : Vaquez , Thrombocythémie essentielle, Métaplasie myéloide
Phase	Phase III
Type étude	Clinique
Médicament	Navitoclax en association avec Ruxolitinib versus Ruxolitinib
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Robert Delage
Coordonnateur	Marie-Claude Lépine 418-649-0252 poste 63401
Statut	Fermé
But étude	Myelofibrosis is a type of bone marrow cancer that usually develops slowly and disrupts body's normal production of blood cells. It causes bone marrow scarring, leading to severe anemia that can cause weakness and fatigue. It can also cause a low number of blood-clotting cells called platelets, which increases risk of bleeding. Myelofibrosis often causes an enlarged spleen. The purpose of this study is to see if a combination of navitoclax and ruxolitinib is more effective and safe in assessment of change in spleen volume when compared to ruxolitinib in participants with myelofibrosis. Navitoclax is an investigational drug for the treatment of myelofibrosis. Participants in this study are divided into two groups, called treatment arms. Each group receives a different treatment. Adult participants with a diagnosis of myelofibrosis will be enrolled. Around 230 participants will be enrolled in approximately 130 sites worldwide. Participants will receive oral navitoclax tablet with oral ruxolitinib tablet or oral ruxolitinib tablet with oral placebo (no active drug) tablet and treatment may continue till the participant cannot tolerate the study drug, or benefit is not achieved, or other reasons which qualify for discontinuation of the study drug. There may be a higher treatment burden for participants in this trial compared to their standard of care. Participants will attend regular visits during the course of the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, Magnetic Resonance Imaging (MRI), bone marrow tests, checking for side effects, and completing questionnaires.
Critères d'éligibilité	• Documented diagnosis of Primary MyeloFibrosis (MF) or Secondary MF (post polycythemia vera [PPV] - MF or Post Essential Thrombocytopenia [PET] - MF) as defined by World Health Organization (WHO) classification. • Must be able to complete the MF Symptom Assessment Form (MFSAF) v4.0 on at least 4 out of 7 days prior to randomization.-- Must have at least 2 symptoms with a score >=3 or a total score of >=12, as measured by the MFSAF v4.0. • Classified as intermediate-2, or high-Risk MF as defined by the Dynamic International Prognostic Scoring System Plus (DIPSS+). • Has splenomegaly defined as spleen palpation measurement >= 5 centimeters (cm) below costal margin or spleen volume greater than or equal to 450 cubic cm as assessed centrally by Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) scan. • Ineligible for stem cell transplantation at time of study entry due to age, comorbidities, or unfit for unrelated or unmatched donor transplant. • Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2.

Critères d'exclusion	• Prior treatment with a Janus Kinase-2 (JAK-2) inhibitor. • Prior treatment with a BH3-mimetic compound or bromodomain and extra-terminal motif (BET) inhibitor. • Receiving medication that interferes with coagulation or platelet function except for low dose aspirin (up to 100 milligram daily) and low molecular weight heparin (LMWH) within 3 days prior to the first dose of study drug or during the study treatment period.