Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of Tamibarotene Plus Azacitidine Versus Placebo Plus Azacitidine in Newly Diagnosed, Adult Patients Selected for RARA-positive Higher-risk Myelodysplastic Syndrome
Protocole ID	SELECT MDS-1
ClinicalTrials.gov ID	NCT04797780
Type(s) de cancer	Syndrome myélodysplasique
Phase	Phase III
Type étude	Clinique
Médicament	Tamibarotene + azacitidine versus placebo + azacitidine
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
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Statut	Actif en recrutement
Date d'activation	01-12-2022
But étude	This study compares the efficacy of Tamibarotene in combination with azacitidine to azacitidine in combination with placebo in participants who are Retinoic Acid Receptor Alpha (RARA) positive, and newly diagnosed with higher-risk myelodysplastic syndrome (MDS), and who have not received treatment for this diagnosis. The primary goal of the study is to compare the complete remission rate between the two treatment arms.
Critères d'éligibilité	• Participants must be at least 18 years old at the time of signing of an informed consent. • Participants must be RARA-positive based on the investigational assay. • Participants must be newly diagnosed with HR-MDS as follows: Diagnosis of MDS according to the World Health Organization (WHO) classification (Arber 2016) and classified by the Revised International Prognostic Scoring System (IPSS R) risk category as very high, high, or intermediate risk. • Participants must have Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤2.
Critères d'exclusion	• Participants are suitable for and agree to undergo allogeneic HSCT at the time of Screening. • Participants who received prior treatment for MDS with any hypomethylating agent, chemotherapy or allogeneic HSCT.