Essai Clinique

Généré le 17 mai 2024 à partir de

Titre	A Phase 2/3, Multicenter, Randomized, Dose Optimization (Part I), Double-blind (Part II) Study to Compare the Efficacy and Safety of Oral Azacitidine (Oral-Aza, ONUREG®) Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Participants With IPSS-R Low- or Intermediate-risk Myelodysplastic Syndrome (MDS)
Protocole ID	CA055-026
ClinicalTrials.gov ID	NCT05469737
Type(s) de cancer	Syndrome myélodysplasique
Phase	Phase II-III
Type étude	Clinique
Médicament	Azacitidine orale
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr John Storring
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Statut	Actif en recrutement
Date d'activation	12-04-2023
But étude	The purpose of this study is to evaluate the safety and efficacy of oral azacitidine in participants with low to intermediate International Prognostic Scoring System Revised (IPSS-R) myelodysplastic syndrome (MDS).
Critères d'éligibilité	• Participant has a documented diagnosis of MDS according to WHO 2016 classification that meets International Prognostic Scoring System Revised (IPSS-R) classification of low- or intermediate-risk disease (IPSS-R score between 1.5 and 4.5). MDS diagnosis, WHO classification, and IPSS-R risk classification will be prospectively determined by independent central pathology and cytogenetics review, and applicable central laboratory results. • Participant must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2.
Critères d'exclusion	• Participants with prior malignancies must have an expected median life expectancy of at least 12 months at the time of inclusion and no active treatment of any sort for at least 24 weeks prior to randomization (including but not limited to immunotherapy or targeted therapy) • Hypoplastic Myelodysplastic Syndrome (MDS) with a marrow cellularity of ≤ 10% • Participants diagnosed with MDS with excess blasts-2 (MDS-EB2) • Prior treatment with azacitidine (any formulation), decitabine, or other hypomethylating agent