




Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	Randomized, Open-label, 2-Arm, Multicenter, Phase 3 Study of Venetoclax and Azacitidine Versus Best Supportive Care as Maintenance Therapy for Patients With Acute Myeloid Leukemia in First Remission After Conventional Chemotherapy
Protocole ID	M19-708 (VIALE-M)
ClinicalTrials.gov ID	NCT04102020
Type(s) de cancer	Leucémie myéloïde aiguë (LMA)
Phase	Phase III
Type étude	Clinique
Médicament	Venetoclax et Azacitidine versus meilleur soin de support
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL  SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr John Storing
Coordonnateur	
Statut	Fermé
But étude	<p>The main objective of this study is to evaluate safety and efficacy of venetoclax in combination with azacitidine (AZA) and best supportive care (BSC) compared to BSC as maintenance therapy in adult participants with acute myeloid leukemia (AML) in first remission after conventional chemotherapy. This study will be conducted in two parts. Part 1 will be the Dose Confirmation portion to determine recommended Phase 3 dose of venetoclax in combination with AZA. Part 2 will be the randomization portion to evaluate if venetoclax in combination with AZA as maintenance therapy improves RFS comparing to BSC. Part 2 begins after Part 1 is completed. During this study, participants will receive venetoclax and azacitidine or best supportive care for approximately 2 years with study visits varying from 1-5 per month. Part 3 will be the Dose Finding portion to determine levels of venetoclax in combination with Azacitidine (CC-486) to be explored. CC-486, and BSC may be administered for up to 24 cycles.</p>
Critères d'éligibilité	<ul style="list-style-type: none">• Diagnosis of newly diagnosed acute myeloid leukemia (AML).• Participant meets the following disease activity criteria:<ul style="list-style-type: none">• Confirmation of AML by World Health Organization (WHO) criteria (2016) and have confirmed complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following completion of planned induction and consolidation chemotherapy.• Achieved first CR + CRi within 4 months of enrollment or be no more than 75 days since last dose of conventional therapy.• AML has intermediate or poor risk cytogenetics per National Comprehensive Cancer Network (NCCN) 2016 criteria.• Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2.• Participant must have adequate hematologic, renal, and liver function laboratory values as described in the protocol.
Critères d'exclusion	<ul style="list-style-type: none">• History of acute promyelocytic leukemia (APL).• History of active central nervous system involvement with acute myeloid leukemia (AML).