# Essai Clinique

Généré le 09 mai 2025 à partir de

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| Titre | A Randomized, Open Label Phase 3 Study Evaluating Safety and Efficacy of Venetoclax in Combination With Azacitidine After Allogeneic Stem Cell Transplantation in Subjects With Acute Myeloid Leukemia |
| Protocole ID | VIALE-T |
| ClinicalTrials.gov ID | NCT04161885 |
| Type(s) de cancer | Leucémie myéloïde aiguë (LMA) |
| Phase | Phase III |
| Type étude | Clinique |
| Médicament | Venetoclax avec azacitidine |
| Institution | CENTRE UNIVERSITAIRE DE SANTE MCGILL<br>SITE GLEN<br>1001 boul. Décarie , Montréal, QC, H4A 3J1 |
| Ville | |
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| Statut | Fermé |
| Date d'activation | 16-12-2022 |
| But étude | The main objective of this study is to evaluate the efficacy of venetoclax in combination with azacitidine to improve Relapse Free Survival (RFS) in Acute Myeloid Leukemia (AML) participants compared to Best Supportive Care (BSC) when given as maintenance therapy following allogeneic stem cell transplantation (SCT).This study will have 2 parts: Part 1 (Dose Confirmation), which may include participants who are greater than or equal to 18 years old; Part 2 (Randomization) which may include participants who are greater than or equal to 12 years old. During Part 1, recommended Phase 3 dose of venetoclax in combination with azacitidine will be determined and during Part 2, the efficacy and safety of venetoclax with azacitidine (Part 2 Arm A) will be compared with BSC (Part 2 Arm B). |
| Critères d'éligibilité | • Participants must be at least 18 years old for Part 1 and, at least 12 years old for Part 2.<br>• Participant must be diagnosed with Acute Myeloid Leukemia (AML) by World Health Organization (WHO) criteria (2017) and either be planning for allogeneic stem cell transplantation or have received allogeneic stem cell transplantation within the past 45 days.<br>• Blast percentage in bone marrow before transplant must be < 10%.<br>• Blast count in peripheral blood must be "0" and Blast percentage in bone marrow must be < 5% after transplant.<br>• Participant meet adequate renal, hepatic and hematologic criteria as described in the protocol.<br>• Participants >= 17 years old must have a Karnofsky Performance Scale (KPS) score > 50 and participants between 12 to 16 years old must have a Lansky Play Performance Scale score > 40. |
| Critères d'exclusion | • History of disease progression during prior treatment with venetoclax.<br>• History of any other malignancy within 2 years prior to study entry, except for: Adequately treated in situ carcinoma of the cervix uteri or carcinoma in situ of breast; basal cell carcinoma of the skin or localized squamous cell carcinoma of the skin; previous malignancy confined and surgically resected (or treated with other modalities) with curative intent; Myelodysplastic Syndrome, Myeloproliferative neoplasm (only allowed if it transformed to AML and AML should be the indication for marrow transplantation). |

- Participant has known infection with HIV or history of being positive for hepatitis B virus (HBV) or hepatitis C virus (HCV) infection.
- Presence of clinical or laboratory symptoms/signs of extramedullary myeloid malignancy.