Essai Clinique

Généré le 08 mai 2024 à partir de

Titre	Thérapie établie en fonction du risque pour traiter la leucémie myéloïde aigüe chez les patients atteints du Syndrome de Down
Protocole ID	AAML1531
ClinicalTrials.gov ID	NCT02521493
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Type étude	Traitement
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL HOPITAL DE MONTREAL POUR ENFANTS 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
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Statut	Fermé
But étude	This phase III trial studies response-based chemotherapy in treating newly diagnosed acute myeloid leukemia or myelodysplastic syndrome in younger patients with Down syndrome. Drugs used in chemotherapy work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Response-based chemotherapy separates patients into different risk groups and treats them according to how they respond to the first course of treatment (Induction I). Response-based treatment may be effective in treating acute myeloid leukemia or myelodysplastic syndrome in younger patients with Down syndrome while reducing the side effects.
Critères d'éligibilité	• Patients must have constitutional trisomy 21 (Down syndrome) or trisomy 21 mosaicism (by karyotype or fluorescence in situ hybridization [FISH]) • Patients with previously untreated de novo AML who meet the criteria for AML with >= 20% bone marrow blasts as set out in the World Health Organization (WHO) Myeloid Neoplasm classification • Patients with cytopenias and/or bone marrow blasts who do not meet the criteria for the diagnosis of AML (WHO Myeloid Neoplasm classification) because of < 20% marrow blasts are eligible if they meet the criteria for a diagnosis of myelodysplastic syndrome (MDS) • Patients with a history of transient myeloproliferative disorder (which may or may not have required chemotherapy intervention), who: • Are > 8 weeks since resolution of transient myeloproliferative disease (TMD) with >= 5% blasts, OR • Patients sho have an increasing blast count (>= 5%) in serial bone marrow aspirates performed at least 4 weeks apart • Children who have previously received chemotherapy, radiation therapy or any anti-leukemic therapy are not eligible for this protocol, with the exception of cytarabine for the treatment of TMD • There are no minimal organ function requirements for enrollment on this study • Note: Previous cardiac repair with sufficient cardiac function is not an exclusion criteria • Each patient's parents or legal guardians must sign a written informed consent • All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human subjects research must be met

Critères d'exclusion	• Patients with promyelocytic leukemia (French-American-British [FAB] M3) • Prior therapy • Patients =< 30 days from the last dose of cytarabine used for treatment of TMD