Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	Greffe allogénique de cellules souches hématopoïétiques chez les enfants et les adolescents atteints de Leucémie Aiguë Lymphoblastique
Protocole ID	FORUM
ClinicalTrials.gov ID	NCT02670564
Type(s) de cancer	Pédiatrique divers
Phase	Phase IV
Type étude	Génétique
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL HOPITAL DE MONTREAL POUR ENFANTS 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
Investigateur principal	Dr David Mitchell
Coordonnateur	Samira Mezziani 514-412-4400 poste 22930
Statut	Actif en recrutement
But étude	Pharmacogenomics (PG) offers the opportunity to individualize treatment according to patient genetic variations which influence activity of enzyme metabolizing or acting in the pathway of prescribed chemotherapy drugsThis add-on research aims to prospectively investigate variations in several candidate genes related to all types of chemotherapeutic drugs and TBI used in the main related study NCT 01949129, THE ALL SCTped FORUM study for their potential role as predictive biomarkers of PK variability and outcome of myeloablative therapy for pediatric patients receiving an allogeneic hematopoietic stem cell transplantation in acute lymphoblastic leukemia.
Critères d'éligibilité	• age at time of screening less than 18 years old • Patients with ALL (except for patients with B-ALL) • indication for allogeneic HSCT • complete remission (CR) before HSCT • written consent of the parents (legal guardian) and, if necessary, the minor patient via "Informed Consent Form" • no pregnancy • no secondary malignancy • no previous HSCT • HSCT is performed in a study participating centre
Critères d'exclusion	• Non Hodgkin-Lymphoma • ALL with extramedullary involvement with indication for TBI • CNS involvement at the timepoint of screening • Trisomy 21 • The whole protocol or essential parts are declined either by patient himself/herself or the respective legal guardian • No consent is given for saving and propagation of anonymous medical data for study reasons • Severe concomitant disease that does not allow treatment according to the protocol at the investigator's discretion (e.g. malformation syndromes, cardiac malformations, metabolic disorders) • Karnofsky / Lansky score < 50% • Subjects unwilling or unable to comply with the study procedures