Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude de phase 2, prospective, à répartition aléatoire, ouverte portant sur l'efficacité potentielle du défibrotide en addition à l'immunoprophylaxie s'inscrivant dans les soins usuels pour la prévention de la maladie du greffon contre l'hôte aiguë chez les patients adultes et pédiatriques après une allogreffe de cellules souches hématopoïétiques
Protocole ID	JZP963-201
ClinicalTrials.gov ID	NCT03339297
Type(s) de cancer	Hémato/Greffe
Phase	Phase II
Type étude	Support
Médicament	Defibrotide
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dre Silvy Lachance
Coordonnateur	Johanne Blais 514-252-3400 poste 3295
Statut	Actif en recrutement
But étude	This is a study comparing the defibrotide prophylaxis arm vs standard of care arm for the prevention of aGvHD.
Critères d'éligibilité	• Patient must be ≥1 year and <75 years of age at screening and undergoing allogeneic HSCT. • Patient must be diagnosed with acute leukemia in morphologic complete remission (CR1 or CR2) or with MDS with no circulating blasts and with less than 5% blasts in the bone marrow • Patient must have planned to receive either a myeloablative or reduced-intensity conditioning regimen and have an unrelated donor who is HLA matched or single-allele mismatched • Patient must receive the following medical regimen as part of standard of care immunoprophylaxis for GvHD in either study arm at doses and regimen determined by local institutional guidelines, physician preference, and patient needMTX or MMF + calcineurin inhibitor (CSA or TAC) +/- ATG (ATG use is limited to 30% of patients). • Graft must be a CD3+ T-cell replete PBSC graft or non-manipulated BM graft. • Adult patients must be able to understand and sign a written informed consent. For pediatric patients, the parent/legal guardian or representative must be able to understand and sign a written informed consent. Assent, when appropriate, will be obtained according to institutional guidelines.
Critères d'exclusion	• Patient has had a prior autologous or allogeneic HSCT. • Patient is using or plans to use an investigational agent for the prevention of GvHD. • Patient is receiving or plans to receive other investigational therapy and/or is enrolled or plans to enroll in a separate clinical study. • Patient, in the opinion of the investigator, may not be able to comply with the safety monitoring requirements of the study. • Patient has a psychiatric illness that would prevent the patient or legal guardian or representative from giving informed consent and/or assent. • Patient has a serious active disease or co-morbid medical condition, as judged by the investigator, which would interfere with the conduct of this study. • Patient is pregnant or lactating and does not agree to stop breastfeeding.

- Any other condition that would cause a risk to the patient if he/she participated in the trial.
- Patient has a known history of hypersensitivity to defibrotide or any of the excipients.