Essai Clinique

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Titre	Une étude randomisée en double aveugle de phase 3 sur l'ibrutinib en association avec des corticostéroïdes par rapport à un placebo en association avec des corticostéroïdes chez des sujets atteints d'une nouvelle poussée de la maladie chronique de la réaction du greffon contre l'hôte (cGVHD)
Protocole ID	PCYC-1140-IM
ClinicalTrials.gov ID	NCT02959944
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Médicament	Ibrutinib et predisone
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
Investigateur principal	Dr Henrique Bittencourt
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Statut	Fermé
But étude	To evaluate the safety and efficacy of ibrutinib in combination with prednisone in subjects with newly diagnosed moderate to severe cGVHD.
Critères d'éligibilité	• 12 Years and older • New onset moderate or severe cGVHD as defined by the 2014 NIH Consensus Development Project Criteria • Need for systemic treatment with corticosteroids for cGVHD • No previous systemic treatment for cGVHD (including extracorporeal photopheresis [ECP]) • May be receiving other immunosuppressants for the prophylaxis or treatment of acute GVHD but the doses of these medications must have been stable for at least 2 weeks prior to Screening • Age ≥12 years old • Karnofsky or Lansky (subjects <16 years) performance status ≥60
Critères d'exclusion	• Received any previous systemic treatment for cGVHD • Inability to begin a prednisone dose ≥0.5 mg/kg/d for the treatment of cGVHD • Any uncontrolled infection or active infection requiring ongoing systemic treatment • Progressive underlying malignant disease or any post-transplant lymphoproliferative disease • Known bleeding disorders • Active hepatitis C virus (HCV) or hepatitis B virus (HBV)