Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Étude de phase 1b/2 du carfilzomib en association avec la dexaméthasone, la mitoxantrone, l'asparaginase pégylée et la vincristine (études d'induction UK R3)chez des enfants atteints de leucémie aigüe lymphoblastique récidivante ou réfractaire
Protocole ID	CFZ008
ClinicalTrials.gov ID	NCT02303821
Type(s) de cancer	Pédiatrique divers
Phase	Phase I-II
Type étude	Traitement
Médicament	carfilzomib
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
Investigateur principal	Dr Henrique Bittencourt
Coordonnateur	Lynda Dufresne 514-345-4931 poste 4969
Statut	Actif en recrutement
But étude	The purpose of the study is to determine the maximum tolerated dose and assess the safety, tolerability and activity of carfilzomib, alone and in combination with induction chemotherapy, in children with relapsed or refractory acute lymphoblastic leukemia (ALL).

Critères d'éligibilité	• Age 21 years or younger at the time of initial ALL diagnosis and age > 1 year at the time of study treatment initiation.
	• Subjects must have a diagnosis of relapsed or refractory ALL with ≥ 5% blasts in the bone marrow (M2 or M3 disease), with or without extramedullary disease. To be eligible, subjects must have had 1 or more prior therapeutic attempts, defined as:
	  • Early first relapse (< 36 months from original diagnosis) after achieving a CR (B-ALL) or first relapse any time following the original diagnosis after achieving a CR (T-ALL)
	  • Relapse after achieving a CR following the first or subsequent relapse (i.e., ≥ 2 relapses) OR
	  • Failing to achieve a CR from original diagnosis after at least 1 induction attempt
	• Subjects must have fully recovered from the acute toxic effects of all previous chemotherapy, immunotherapy, or radiotherapy treatment before enrollment.
	• Subjects must have a serum creatinine level that is ≤ 1.5 × institutional upper limit of normal (ULN) according to age. If serum creatinine level is > 1.5 × ULN, the subject must have a calculated creatinine clearance or radioisotope glomerular filtration rate (GFR) ≥ 70 mL/min/1.73 m2.
	• Adequate liver function, defined as both of the following:
	  • Total bilirubin ≤ 1.5 × institutional ULN except in the presence of Gilbert Syndrome
	  • Alanine aminotransferase (ALT) ≤ 5 × institutional ULN
	• Performance status: Karnofsky or Lansky scores ≥ 50 for subjects > 16 years old or ≤ 16 years old, respectively.

Critères d'exclusion	• Known allergy to any of the drugs used in the study. (Subjects who have had a previous allergy to PEG-asparaginase but can receive Erwinia are eligible.)
	• Known allergy to Captisol (a cyclodextrin derivative used to solubilize carfilzomib)
	• Left ventricular fractional shortening < 30%
	• History of ≥ Grade 2 pancreatitis
	• Active graft?versus?host disease requiring systemic treatment
	• Positive culture for or other clinical evidence of infection with bacteria or fungus within 14 days of the initiation of study treatment
	• Down Syndrome
	• Prior therapy restrictions:
	  • Subjects must have completed therapy with granulocyte?colony stimulating factor (G?CSF) or other myeloid growth factors at least 7 days before study treatment initiation, or at least 14 days before study treatment initiation, if pegylated myeloid growth factors were administered.
	  • Subjects must have completed any type of active immunotherapy (e.g., tumor vaccines) at least 42 days before study treatment initiation.
	  • At least 3 antibody half?lives must have elapsed since the last dose of monoclonal antibody (e.g., 66 days for rituximab and 69 days for epratuzumab) before subjects may initiate study treatment.
	  • Subjects must have completed any type of active immunotherapy (e.g., tumor vaccines) at least 42 days before study treatment initiation.
	  • Subjects must not have received other antineoplastic agents with therapeutic intent, excluding hydroxyurea and antimetabolites administered as part of maintenance chemotherapy, within 7 days prior to study treatment initiation