Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Étude de phase II visant à évaluer le ruxolitinib, un inhibiteur de JAK1/JAK2, en association avec la chimiothérapie chez des enfants atteints de leucémie aiguë lymphoblastique de novo à risque élevé présentant un réarrangement de CRLF2 et/ou une mutation dans la voie JAK
Protocole ID	COG-AALL1521
ClinicalTrials.gov ID	NCT02723994
Type(s) de cancer	Pédiatrique divers
Phase	Phase II
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
Investigateur principal	Dr Yvan Samson
Coordonnateur	Clemence Noury 514-345-4931 poste 6848
Statut	Actif en recrutement
But étude	This is a nonrandomized study of ruxolitinib in combination with a standard multi-agent chemotherapy regimen for the treatment of B-cell acute lymphoblastic leukemia. Part 1 of the study will optimize the dose of study drug (ruxolitinib) in combination with the chemotherapy regimen. Part 2 will evaluate the efficacy of combination chemotherapy and ruxolitinib at the recommended dose determined in Part 1.

Critères d'éligibilité	• De novo high-risk (HR) Ph-like B-ALL for which any of following criteria are present at diagnosis:
	  • Age ≥ 10 years
	  • White blood cell (WBC) ≥ 50 × 10^3/μL
	  • CNS3 leukemia
	• One of the following Ph-like ALL genetic lesions must be present in the diagnostic bone marrow or peripheral blood sample:
	  • CRLF2 rearrangement with JAK1 or JAK2 mutation (JAK+)
	  • CRLF2 rearrangement without JAK mutation
	  • Other JAK pathway alterations (eg, JAK2 fusions, erythropoietin receptor (EPO-R) fusions, SH2B3 deletions, interleukin-7 receptor-alpha (IL7RA) mutations) with or without CRLF2 rearrangement
	• Completed a 4-drug Induction therapy regimen (modified aBFM regimen or equivalent) in Study AALL1131 or as the institutional standard of care for HR B-ALL and have had end-Induction minimal residual disease (MRD) assessed
	• Male and female subjects of reproductive non childbearing potential or willing to take appropriate precautions to avoid pregnancy or fathering a child for the duration of study participation

Critères d'exclusion	• Receipt of any other cytotoxic chemotherapy before Induction therapy, with exception of hydroxyurea or steroid pretreatment • Trisomy 21 (Down syndrome) • BCR-ABL1-rearranged (Ph+) ALL • Calculated creatinine clearance or radioisotope glomerular filtration rate < 70 mL/min/1.73 m^2 • Alanine aminotransferase ≥ 3 × upper limit of normal (ULN) for age • Direct bilirubin ≥ 1.5 × ULN (may be assumed if total bilirubin is below ULN) • History or evidence of cirrhosis • Platelet count < 75 × 10^3/μL • Absolute neutrophil count (ANC) < 750/μL • Positive screen for hepatitis B or C • Known human immunodeficiency virus infection