Essai Clinique

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Titre	Étude internationale de phase 3 sur la leucémie lymphoblastique aiguë à chromosome Philadelphie (LL Ph +) de Philadelphie testant l'imatinib en association avec deux épines dorsales de chimiothérapie cytotoxique
Protocole ID	COG-AALL1631
ClinicalTrials.gov ID	NCT03007147
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Médicament	imatinib
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
Investigateur principal	Dr Henrique Bittencourt
Coordonnateur	Clemence Noury 514-345-4931 poste 6848
Statut	Actif en recrutement
But étude	This randomized phase III trial studies how well imatinib mesylate and combination chemotherapy work in treating patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia. Imatinib mesylate may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Drugs used in chemotherapy, work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving imatinib mesylate and combination chemotherapy may work better in treating patients with Philadelphia chromosome positive acute lymphoblastic leukemia.

Critères d'éligibilité	• Patients who have not previously enrolled on AALL08B1 or APEC14B1 (if open for classification of newly diagnosed ALL patients) prior to enrollment on AALL1631, a baseline diagnostic sample must be available to develop an MRD probe
	• Newly diagnosed de novo ALL (B-ALL or T-ALL) with definitive evidence of BCR-ABL1 fusion by karyotype, fluorescence in situ hybridization (FISH) and/or reverse transcriptase (RT)-PCR
	  • For patients who DO NOT enter AALL1631 via AALL08B1 or APEC14B1 (if open for classification of newly diagnosed ALL patients), laboratory reports detailing evidence of BCR-ABL1 fusion must be submitted for rapid central review within 72 hours of study enrollment
	  • Patients with known chronic myelogenous leukemia (CML) who develop lymphoid blast crisis are not eligible
	• Patient must have previously started induction therapy, which includes vincristine, a corticosteroid, pegaspargase, with or without anthracycline, and/or other standard cytotoxic chemotherapy
	• Patient has not received more than 14 days of induction therapy
	• Patient has not had prior treatment with imatinib, dasatinib, or any other BCR-ABL1 inhibitor
	• Karnofsky/Lansky performance status >= 60; use Karnofsky for patients > 16 years of age and Lansky for patients =< 16 years of age
	• Direct bilirubin =< 2.0 mg/dL
	• Shortening fraction of >= 27% by echocardiogram
	• Ejection fraction of >= 50% by radionuclide angiogram or echocardiogram
	• Corrected QT interval, QTc < 480 msec
	  • Note: Repeat echocardiogram is not required if echocardiogram was obtained within 21 days of study enrollment
	• Creatinine clearance or radioisotope glomerular filtration rate (GFR) >= 70 mL/min/1.73 m^2
	• Serum creatinine within normal limits based on age/gender, as follows:
	  • 1 to < 2 years: maximum serum creatinine 0.6 mg/dL (both male and female)
	  • 2 to < 6 years: maximum serum creatinine 0.8 mg/dL (both male and female)

	• 6 to < 10 years: maximum serum creatinine 1 mg/dL (both male and female) • 10 to < 13 years: maximum serum creatinine 1.2 mg/dL (both male and female) • 13 to < 16 years: maximum serum creatinine 1.5 mg/dL (male), 1.4 mg/dL (female) • >= 16 years: maximum serum creatinine 1.7 mg/dL (male), 1.4 mg/dL (female)

Critères d'exclusion	• Known history of chronic myelogenous leukemia (CML)
	• ALL developing after a previous cancer treated with cytotoxic chemotherapy
	• Active, uncontrolled infection, or active systemic illness that requires ongoing vasopressor support or mechanical ventilation
	• Down syndrome
	• Pregnancy and breast feeding
	  • Female patients who are pregnant; a pregnancy test is required for female patients of childbearing potential
	  • Lactating females who plan to breastfeed their infants
	  • Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation
	• Patients with congenital long QT syndrome, history of ventricular arrhythmias or heart block