Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	Étude de phase III, randomisée, stratifiée selon le risque pour évaluer le blinatumomab dans le traitement d'une première rechute d'une leucémie lymphoblastique aiguë à cellules B chez les enfants.
Protocole ID	AALL1331
ClinicalTrials.gov ID	NCT02101853
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Stade	Récidive
Type étude	Traitement
Médicament	Blinatumomab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL HOPITAL DE MONTREAL POUR ENFANTS 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
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Statut	Fermé
But étude	This randomized phase III trial studies how well blinatumomab works compared with standard combination chemotherapy in treating patients with B-cell acute lymphoblastic leukemia that has returned after a period of improvement (relapsed). Monoclonal antibodies, such as blinatumomab, may interfere with the ability of tumor cells to grow and spread. It is not yet known whether standard combination chemotherapy is more effective than blinatumomab in treating relapsed B-cell acute lymphoblastic leukemia.
Critères d'éligibilité	• First relapse of B-ALL, allowable sites of disease include isolated bone marrow, combined bone marrow and CNS and/or testicular, and isolated CNS and/or testicular; extramedullary sites are limited to the CNS and testicles • No waiting period for patients who relapse while receiving standard maintenance therapy • Patients who relapse on frontline therapy in phases other than maintenance must have fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy prior to entering this study • Cytotoxic therapy: at least 14 days since the completion of cytotoxic therapy with the exception of hydroxyurea, which is permitted up to 24 hours prior to the start of protocol therapy, or maintenance chemotherapy, or intrathecal chemotherapy (methotrexate strongly preferred) administered at the time of the required diagnostic lumbar puncture to establish baseline CNS status • Biologic (anti-neoplastic) agent: at least 7 days since the completion of therapy with a biologic agent; for agents that have known adverse events occurring beyond 7 days after administration, this period must be extended beyond the time during which adverse events are known to occur • Stem cell transplant or rescue: patient has not had a prior stem cell transplant or rescue • Patient has not had prior treatment with blinatumomab • With the exception of intrathecal chemotherapy (methotrexate strongly preferred) administered at the time of the required diagnostic lumbar puncture to establish baseline CNS status, patient has not received prior relapse-directed therapy (i.e., this protocol is intended as the INITIAL treatment of first relapse)

	• Patients must have a performance status corresponding to Eastern Cooperative Oncology Group (ECOG) scores of 0, 1, or 2; use Karnofsky for patients > 16 years of age and Lansky for patients =< 16 years of age • Creatinine clearance or radioisotope glomerular filtration rate (GFR) >= 70 mL/min/1.73 m^2 or a serum creatinine based on age/gender as follows: • 1 to < 2 years: =< 0.6 mg/dL • 2 to < 6 years: =< 0.8 mg/dL • 6 to < 10 years: =< 1 mg/dL • 10 to < 13 years: =< 1.2 mg/dL • 13 to < 16 years: =< 1.5 mg/dL (males) and =< 1.4 mg/dL (females) • >= 16 years: =< 1.7 mg/dL (males) and =< 1.4 mg/dL (females) • Direct bilirubin < 3.0 mg/dL • Shortening fraction of >= 27% by echocardiogram, or • Ejection fraction of >= 50% by radionuclide angiogram • All patients and/or their parent or legal guardian must sign a written informed consent • All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met
Critères d'exclusion	• Patients with Philadelphia chromosome positive/breakpoint cluster region protein (BCR)-Abelson murine leukemia viral oncogene homolog 1 (ABL1)+ ALL are not eligible • Patients with Burkitt leukemia/lymphoma or mature B-cell leukemia are not eligible • Patients with T-lymphoblastic leukemia (T-ALL)/lymphoblastic lymphoma (T-LL) are not eligible • Patients with B-lymphoblastic lymphoma (B-LL) are not eligible • Patients with known optic nerve and/or retinal involvement are not eligible; patients who are presenting with visual disturbances should have an ophthalmologic exam and, if indicated, a magnetic resonance imaging (MRI) to determine optic nerve or retinal involvement • Patients known to have one of the following concomitant genetic syndromes: Down syndrome, Bloom syndrome, ataxia-telangiectasia, Fanconi anemia, Kostmann syndrome, Shwachman syndrome or any other known bone marrow failure syndrome • Patients with known human immunodeficiency virus (HIV) infection • Patients with known allergy to mitoxantrone, cytarabine, or both etoposide and etoposide phosphate (Etopophos) • Lactating females who plan to breastfeed • Patients who are pregnant; pregnancy test is required for female patients of childbearing potential • 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 pre-existing significant central nervous system pathology that would preclude treatment with blinatumomab, including: history of severe brain injury, dementia, cerebellar disease, organic brain syndrome, psychosis, coordination/movement disorder, or autoimmune disease with CNS involvement are not eligible; patients with a history of cerebrovascular ischemia/hemorrhage with residual deficits are not eligible; (patients with a history of cerebrovascular ischemia/hemorrhage remain eligible provided all neurologic deficits have resolved) • Patients with uncontrolled seizure disorder are not eligible; (patients with seizure disorders that do not require antiepileptic drugs, or are well controlled with stable doses of antiepileptic drugs remain eligible)