Essai Clinique

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Titre	Une étude de phase III randomisée du brentuximab védotine (SGN-35) et des chimiothérapies d'association dans le traitement des lymphomes de Hodgkin classiques (LHc) à risque élevé nouvellement diagnostiqués chez les enfants et les adolescents.
Protocole ID	COG-AHOD1331
ClinicalTrials.gov ID	NCT02166463
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Type étude	Traitement
Médicament	Brentuximab Vedotin
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Statut	Fermé
But étude	This randomized phase III trial studies brentuximab vedotin and combination chemotherapy to see how well they work compared to combination chemotherapy alone in treating younger patients with newly diagnosed Hodgkin lymphoma. Combinations of biological substances in brentuximab vedotin may be able to carry cancer-killing substances directly to Hodgkin lymphoma cells. Drugs used in chemotherapy, such as doxorubicin hydrochloride, bleomycin sulfate, vincristine sulfate, etoposide, prednisone, and cyclophosphamide, 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. It is not yet known if combination chemotherapy is more effective with or without brentuximab vedotin in treating Hodgkin lymphoma.
Critères d'éligibilité	• Patients with newly diagnosed, pathologically confirmed cHL meeting one of the following Ann Arbor stages are eligible: • Stage IIB with bulk • Stage IIIB • Stage IVA • Stage IVB • If study eligibility by staging is uncertain, consultation with Imaging and Radiation Oncology Core (IROC) Rhode Island (RI) may be obtained prior to study enrollment • 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: • 2 to < 6 years: male 0.8 mg/dL, female 0.8 mg/dL • 6 to < 10 years: male 1 mg/dL, female 1 mg/dL • 10 to < 13 years: male 1.2 mg/dL, female 1.2 mg/dL • 13 to < 16 years: male 1.5 mg/dL, female 1.4 mg/dL • >= 16 years: male 1.7 mg/dL, female 1.4 mg/dL • Total bilirubin =< 1.5 x upper limit of normal (ULN) for age • Serum glutamic oxaloacetic transaminase (SGOT) (aspartate transaminase [AST]) or serum glutamate pyruvate transaminase (SGPT) (alanine transaminase [ALT]) < 2.5 x upper limit of normal (ULN) for age • Shortening fraction of >= 27% by echocardiogram, or ejection fraction of >= 50% by radionuclide angiogram • Forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) > 60% by pulmonary function test (PFT), unless due to large mediastinal mass from Hodgkin lymphoma (HL)

	• For children who are unable to cooperate for PFTs, the criteria are: no evidence of dyspnea at rest, no exercise intolerance, and a pulse oximetry reading of > 92% on room air • All patients and/or their parents or legal guardians 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 nodular lymphocyte-predominant HL • Patients with an immunodeficiency that existed prior to diagnosis, such as primary immunodeficiency syndromes, organ transplant recipients and children on current systemic immunosuppressive agents are not eligible • Patients who are pregnant; (a negative pregnancy test is required for female patients of childbearing potential) • Lactating females who plan to breastfeed • Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation and for 30 days after the last dose of chemotherapy • Patients known to be positive for human immunodeficiency virus (HIV) are not eligible • Patients who have received any previous chemotherapy or radiation therapy are not eligible • Patients who received systemic corticosteroids within 28 days of enrollment on this protocol, except as specified, are not eligible