Essai Clinique

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Titre	A Randomized Phase 3 Trial of Nivolumab in Combination With Chemo-Immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-Cell Lymphoma
Protocole ID	COG-ANHL1931
ClinicalTrials.gov ID	NCT04759586
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase III
Type étude	Clinique
Médicament	Nivolumab en association avec de la chimio-immunothérapie
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL CHUL ET CENTRE MERE-ENFANT SOLEIL 2705 boulevard Laurier, Québec, QC, G1V 4G2
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Investigateur principal	Dr Bruno Michon
Coordonnateur	
Statut	Actif en recrutement
Date d'activation	27-09-2022
But étude	This phase III trial compares the effects of nivolumab with chemo-immunotherapy versus chemo-immunotherapy alone in treating patients with newly diagnosed primary mediastinal B-cell lymphoma (PMBCL). Immunotherapy with monoclonal antibodies, such as nivolumab, may help the body's immune system attack the cancer, and may interfere with the ability of cancer cells to grow and spread. Treatment for PMBCL involves chemotherapy combined with an immunotherapy called rituximab. Chemotherapy drugs 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. Rituximab is a monoclonal antibody. It binds to a protein called CD20, which is found on B cells (a type of white blood cell) and some types of cancer cells. This may help the immune system kill cancer cells. Giving nivolumab with chemo-immunotherapy may help treat patients with PMBCL.

Critères d'éligibilité	• Age >= 2 years
	• Patient must have histologically confirmed primary mediastinal B-cell lymphoma (PMBCL) as defined by World Health Organization (WHO) criteria
	• Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 or ECOG performance status of 3 if poor performance is related to lymphoma
	  • Children's Oncology Group (COG) Institutions: Use Karnofsky for patients >= 17 and < 18 years of age and Lansky for patients < 17 years of age
	• Adults (age 18 or older): Creatinine clearance >= 30 mL/min, as estimated by the Cockcroft and Gault formula. The creatinine value used in the calculation must have been obtained within 28 days prior to registration. Estimated creatinine clearance is based on actual body weight
	• Pediatric Patients (age < 18 years): The following must have been obtained within 14 days prior to registration:
	  • Measured or calculated (based on institutional standard) creatinine clearance or radioisotope glomerular filtration rate (GFR) >= 70 ml/min/1.73 m^2, or
	  • Serum creatinine =< 1.5 x institutional upper limit of normal (IULN), or a serum creatinine based on age/gender as follows:
	  • Age : 2 to < 6 year; Maximum serum creatinine (mg/dL): 0.8 (male; 0.8 (female)
	  • Age : 6 to < 10 years; Maximum serum creatinine (mg/dL): 1 (male); 1 (female)
	  • Age : 10 to < 13 years; Maximum serum creatinine (mg/dL): 1.2 (male); 1.2

	(female) • Age : 13 to < 16 years; Maximum serum creatinine (mg/dL): 1.5 (male); 1.4 (female) • Age : >= 16 years to < 18 years; Maximum serum creatinine (mg/dL): 1.7 (male); 1.4 (female) • Patients with abnormal liver function will be eligible to enroll if the lab abnormality is thought to be due to the lymphoma or Gilbert's syndrome • Age >= 18 years: Ejection fraction of >= 50% by echocardiogram • Age < 18 years: Shortening fraction of >= 27% by echocardiogram, or ejection fraction of >= 50% by radionuclide angiogram • Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial • For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated • Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load • 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	• Administration of prior anti-cancer therapy except as outlined below: • A short course (=< 2 weeks) of corticosteroids for the relief of lymphoma-related symptoms • A single course of COP (cyclophosphamide, vincristine, and prednisone) • One cycle of chemo-immunotherapy including R-CHOP, DA-EPOCH-R, or a pediatric mature B-cell non-Hodgkin lymphoma (B-NHL) induction therapy (such as ANHL1131) that has not started more than 21 days prior to enrollment • Active ischemic heart disease or heart failure • Active uncontrolled infection • Central nervous system (CNS) involvement of lymphoma • Previous cancer that required systemic chemotherapy and/or thoracic radiation. Other cancers will be permitted if in remission x 3 years • Active autoimmune disease that has required systemic treatment (such as disease modifying agents, corticosteroids, or immunosuppressive agents) in the past 2 years. Replacement therapy such as thyroxine, insulin or physiologic corticosteroid for adrenal or pituitary insufficiency is not considered a form of systemic treatment • In patients < 18 years of age hepatitis B serologies consistent with past or current infections • Patients with severe hepatic impairment (Child-Pugh class C or serum total bilirubin > 5.0 mg/dL) unless thought to be due to lymphoma or Gilbert's syndrome • Female patients who are pregnant since fetal toxicities and teratogenic effects have been noted for several of the study drugs. A pregnancy test is required for female patients of childbearing potential • Sexually active patients of reproductive potential who have not agreed to use a highly effective contraceptive method (failure rate of < 1% per year when used consistently and correctly) for the duration of their study participation • Lactating females are not eligible unless they have agreed not to breastfeed their infants starting with the first dose of study therapy and for at least 6 months after the last dose of rituximab