Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	Phase 2 Study of Pembrolizumab and Chemotherapy in Patients With Newly Diagnosed Classical Hodgkin Lymphoma
Protocole ID	MK-3475-C11 (KEYNOTE-C11)
ClinicalTrials.gov ID	NCT05008224
Type(s) de cancer	Hodgkin (Maladie de)
Phase	Phase II
Type étude	Clinique
Médicament	Pembrolizumab avec chimiothérapie
Institution	CIUSSS DU NORD-DE-L'ILE-DE-MONTREAL HOPITAL DU SACRE-COEUR-DE-MONTREAL 5400 boul. Gouin Ouest, Montréal, QC, H4J1C5
Ville	
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Statut	Fermé
But étude	The purpose of this study is to evaluate the safety and efficacy of pembrolizumab (MK-3475) monotherapy, followed by chemotherapy, followed by pembrolizumab consolidation. The primary hypothesis of the study is that the complete response (CR) rate at the end of study intervention according to Lugano 2014 response criteria is higher than conventional chemotherapy.
Critères d'éligibilité	The main inclusion criteria include, but are not limited to the following: • Has a histologically confirmed diagnosis of Ann Arbor Stage III or IV classical Hodgkin Lymphoma (cHL). Stage I and II participants may be enrolled, but must have at least one National Comprehensive Cancer Network (NCCN) unfavorable risk factor per protocol • Has measurable 2-fluorodeoxyglucose (FDG)-avid disease based on investigator assessment according to Lugano 2014 response criteria • Has not received prior radiation therapy, chemotherapy, immunotherapy, or other systemic therapy for the treatment of cHL before the first dose of study intervention • Has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1 assessed within 7 days before the start of study intervention
Critères d'exclusion	The main exclusion criteria include, but are not limited to the following: • Has confirmed nodular lymphocyte-predominant Hodgkin Lymphoma (HL) • Has an uncontrolled intercurrent cardiovascular illness • Has received prior therapy with an anti-programmed cell death 1 protein (PD-1), anti-programmed cell death ligand 1 protein (PD-L1), or anti- programmed cell death ligand 2 protein (PD-L2) agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor • Has received or is expected to receive a live or live-attenuated vaccine within 30 days before the first dose of study intervention • Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks before the first dose of study intervention • Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of study medication • Has a known additional malignancy that is progressing or has required active treatment within the past 5 years

- Has radiographically detectable central nervous system metastases and/or carcinomatous meningitis
- Has an active autoimmune disease that has required systemic treatment in past 2 years
- Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease
- Has a history or current evidence of pulmonary fibrosis
- Has had an allogenic tissue/solid organ transplant