



Essai Clinique

Généré le 17 avr. 2024 à partir de

Titre	Une étude ouverte de phase I/II sur l'innocuité et l'efficacité des lymphocytes T propres au virus d'Epstein-Barr (VEB) pour le traitement d'une infection au VEB ou de maladies lymphoprolifératives liées au VEB
Protocole ID	EBV-TCL-01
ClinicalTrials.gov ID	NCT02580539
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase I-II
Type étude	Traitement
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL  PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dr Jean-Sébastien Delisle
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Statut	Actif en recrutement
But étude	This study evaluates the safety and efficacy of EBV-specific T-cell lines to treat patients suffering from high EBV viral titers not responding to standard of care therapies and to treat EBV-related lymphoma. The study will recruit 6 patients to receive autologous T cells or a T cell line derived from the patient's allogeneic donor (in the case of stem cell transplant recipients), and 6 patients to receive a T-cell line prepared from a matched or partially matched related donor.
Critères d'éligibilité	• Capacity to provide informed consent • Age $\geq$ 18 years old • Confirmed treatment-refractory EBV reactivation or EBV-related lymphoma • ECOG of 2 or less DONOR ELIGIBILITY: An allogeneic donor must be a first-degree relative with at least 3/6 HLA compatibility, have consented to donate peripheral blood mononuclear cells, and fulfill the same criteria for stem cell donation according to the hospital's standard operating procedure.
Critères d'exclusion	• Medical condition requiring a corticosteroid dose greater than Prednisone 0.5mg/kg/day (or equivalent) at the time of the infusion. • Patient has received T-cell depleting antibodies or stem cell transplantation in the 28 days prior to proposed date of anti-EBV T-cell line infusion • Patient has received a solid organ transplant in the 3 months prior to proposed date of anti-EBV T-cell line infusion. • Pregnant or nursing females • Life expectancy of less than 3 months due to a condition unrelated to the EBV- related disease. • Active uncontrolled GVHD • Active uncontrolled SOT rejection episode