Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Une étude ouverte de phase I-II de greffe allogénique non-myéloablative utilisant le sang de cordon amplifié avec ECT-001 (UM171/ FED-BATCH CULTURE SYSTEM) pour le traitement des myélomes multiples à haut risque.
Protocole ID	ECT001-003
ClinicalTrials.gov ID	NCT03441958
Type(s) de cancer	Myélome
Phase	Phase I-II
Stade	Myélome multiple
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	Montreal
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Statut	Fermé
But étude	This is a single institution, prospective, phase I/II open-label study in a maximum of 20 patients evaluating a novel treatment strategy in NDMM patients with high-risk disease who do not have a 6/6 compatible sibling donor. Participating patients will be from Hôpital Maisonneuve-Rosemont (HMR) or referred to HMR for this protocol. Newly diagnosed multiple myeloma patients will be evaluated for eligibility before or during the autologous stem cell transplant (ASCT) period. After a Bortezomib-based induction treatment (VTD, CyBorD, RVD or PAD [in patients with plasma cell leukemia]) for a minimum of 4 cycles, followed by Melphalan ≥ 140 mg/m2 and ASCT, eligible patients who accept to participate will undergo screening evaluation to receive a non myeloablative (NMA) allogeneic HSCT with ECT-001 expanded CB. It is estimated that 18 months will be necessary to enroll the targeted sample size. Once eligibility has been confirmed, study treatment will begin. After an ASCT, eligible patients will receive a conditioning regimen before receiving an outpatient NMA allogeneic HSCT with an ECT-001 expanded CB on day 0. Patients will be followed at least every week for the first 3 months, then every month, in the absence of GVHD, for disease evaluation and adverse events. Occurrence and severity of acute GVHD will be evaluated using the modified Glucksberg176 and IBMTR177 criteria, while chronic GVHD will be evaluated using the NIH178 criteria.
Critères d'éligibilité	• Age 18-65 years. • Newly diagnosed multiple myeloma using the International Myeloma Working Group criteria with measurable disease and any of the following:i. t(4;14), t(14;16), t(14;20), del(17p13), chromosome 1 abnormalities with ISS II or III; ii. Revised-ISS 3; iii. Primary plasma cell leukemia; iv. Refractory to first line triplet Bortezomib-based induction treatment. v. ≥ 2 cytogenetics abnormalities as defined above regardless of ISS stage • Received a first line triplet Bortezomib-induction regimen for a minimum of 4 cycles with achievement of at least partial response; or received a doublet or triplet Lenalidomide-based second line induction treatment with at least partial response for patients refractory to Bortezomib in first line. • Received high-dose Melphalan ≥ 140 mg/m2 followed by ASCT. • Availability of a cord blood with an HLA match ≥ 5/8 and < 8/8 meeting the following requirements: CD34+ cell count ≥ 0.5 x 105/kg and nucleated cell count >= 1.5 x 107/kg.

Critères d'exclusion	• Having previously received two ASCT. • Having previously received autologous-allogeneic tandem transplantation. • Having received more than 4 months of maintenance with Lenalidomide or Bortezomib after ASCT. • Poor organ function defined as either: forced vital capacity, forced expiratory volume in 1 second or lung diffusing capacity of carbon monoxide corrected for hemoglobin < 50%, left ventricular ejection fraction < 40% (evaluated by either echocardiogram or MUGA), uncontrolled arrhythmia or symptomatic cardiac disease, creatinine clearance < 60 mL/minute. • Karnofsky score < 70% or comorbidity index HCT-CI > 3. • Bilirubin > 2 x upper limit of normal (ULN) unless felt to be related to Gilbert's disease or hemolysis; AST and ALT > 2.5 x ULN; alkaline phosphatase > 5 x ULN; liver cirrhosis. • Non secretory disease or non-measurable disease in serum or urine at time of diagnosis. • Uncontrolled infection. • Active infection with any of the following viruses: HIV, HTLV-1 or 2, hepatitis B or C. • Presence of another malignancy with an expected survival estimated < 75% at 5 years. • Suspicion of cardiac amyloidosis. • Current history of drug and/or alcohol abuse. • Availability of a matched sibling donor. • Pregnancy, breastfeeding or unwillingness to use appropriate contraception. • Participation in a trial with an investigational agent within 30 days prior to entry in the study. • Patient unable to give informed consent or unable to comply with the treatment protocol including appropriate supportive care, follow-up and tests. • Any abnormal condition or laboratory result that is considered by the principal investigator capable of altering patient's condition or study outcome.