# Essai Clinique

Généré le 05 mai 2024 à partir de

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| Titre | Étude ouverte de phase II portant sur l'administration de lénalidomide et de dexaméthasone suivie de perfusions de lymphocytes issus d'un donneur pour le traitement du myélome multiple récidivant après une greffe allogénique de cellules souches |
| Protocole ID | HMR003 |
| ClinicalTrials.gov ID | NCT03413800 |
| Type(s) de cancer | Myélome |
| Phase | Phase II |
| Stade | Récidive |
| Type étude | Traitement |
| Institution | CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL<br>PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX<br>5415 boul. de l'Assomption, Montréal, QC, H1T2M4 |
| Ville | Montréal |
| Investigateur principal | Dr Jean Roy |
| Coordonnateur | Nathalie Lachapelle<br>514-252-3400 poste 4471 |
| Statut | Fermé |
| But étude | This study proposes the powerful combination of the two following goals, one clinical and one biological :<br>1. Clinical: The investigators propose a two-step treatment using first Len in association with Dexamethasone (Dex), followed by Donor Leukocytes Infusions (DLIs) to offer an optimal disease control strategy in relapsed patients. The cytoreductive and immunomodulatory effects of Len is expected to induce a permissive immunological environment for the immunotherapeutic activity of DLIs to develop, while the association with Dex will lessen the risk of graft-versus-host disease (GVHD). This treatment combination has the potential to further improve depth of myeloma response, delay myeloma progression and improve patient survival.<br>2. Biological: In an attempt to gain knowledge on how the GvMM behaves in MM patients post-relapse after having received a combined treatment of Len/Dex/DLIs, the investigators propose to characterize the immune environment of their bone marrow (BM) using both minimal residual disease (MRD) assessement by flow cytometry and an unbiased analysis of the transcriptome at various time points. |
| Critères d'éligibilité | • Age 18-65 years<br>• Myeloma patients in first relapse after a sibling or unrelated allogeneic stem cell transplantation<br>• Patients with measurable disease at time of relapse based on the IMWG criteria<br>• All study participants must comply with the Revlimid Pregnancy Prevention Plan.<br>• Females of reproductive potential must adhere to the scheduled pregnancy testing as required in the Revlimid Pregnancy Prevention Plan. |
| Critères d'exclusion | • Relapse occurred within 180 days post allograft<br>• Refractory to Len at any given time before allogeneic transplantation<br>• Presence of ≥ grade II or uncontrolled acute GVHD<br>• Presence of severe or uncontrolled chronic GVHD<br>• Karnofsky score < 70%<br>• Bilirubin > 50 µmol/L unless felt to be related to Gilbert's disease or hemolysis; AST and ALT > 5 x upper limit of normal (ULN); alkaline phosphatase > 5 x ULN<br>• Known hypersensitivity to Len or Dex<br>• Active infection with any of the following viruses: HIV, HTLV-1 or 2, hepatitis B (defined as |

HBsAg positivity) or hepatitis C (defined as anti-HCV positivity or HCV-RNA positivity)
- Presence of another malignancy with an expected survival estimated < 75% at 5 years (complete resection of basal cell carcinoma or squamous cell carcinoma, complete resection of a ductal carcinoma in situ, presence of lobular carcinoma in situ, complete resection of carcinoma in situ of the cervix, or an in situ or low-risk prostate cancer after curative therapy are not exclusion criteria)
- Positive beta-human chorionic gonadotropin pregnancy test, to be performed in all women of childbearing potential at screening and baseline. Female study participants who are surgically sterile (hysterectomy) or who have been postmenopausal for at least 12 consecutive months are automatically eligible for this criterion
- Females of child-bearing potential not agreeing to remain abstinent or to use 2 simultaneous effective methods of contraception from at least 4 weeks before, to at least 4 weeks following discontinuation of Len. Males not agreeing to use a condom during any sexual contact with females of child-bearing potential from at least 4 weeks before, to at least 4 weeks following discontinuation of Len
- Women who are lactating
- Female of child-bearing potential who are planning to become pregnant while enrolled in this study up to 4 weeks after the last Len dose
- Participation in a trial with an investigational agent within 30 days prior to entry in the study
- Inability to provide written informed consent prior to initiation of any study-related procedures, or inability, in the opinion of investigators, to comply with all requirements of the study
- Estimated probability to survive less than 6 months after initiation of Len and Dex
- Current history of drug and/or alcohol abuse
- Any abnormal condition or laboratory result that is considered by investigators capable of altering patient's condition, compliance or study outcome
- Any patient who, in the opinion of investigators, should not participate in this study
- Having received allogeneic stem cell transplantation in relapse after autologous transplant.
- Having received Len therapy after allogeneic transplant, before relapse
- Poor organ function defined as either: diffusing capacity of the lung for carbon monoxide corrected for hemoglobin using Dinakara method (DLCOc) < 50%; forced expiratory volume in 1 second < 50%; left ventricular ejection fraction (LVEF) < 40% evaluated by echocardiogram or multi-gated acquisition scan (MUGA); uncontrolled arrhythmia; symptomatic cardiac disease; creatinine clearance < 30 mL/minute; liver cirrhosis