MT2024-05: A Phase I, First in Human Open Label Study to Evaluate the Safety and Tolerability of TRX103 cell infusion in subjects with hematological malignancies undergoing HLA-mismatched related or unrelated hematopoietic stem cell transplantation (HSCT)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- undergoing mismatched related (haploidentical) or unrelated allogeneic hematopoietic stem cell transplantation (HSCT) - diagnosis of one of the following hematologic malignancies: Acute Lymphoblastic Leukemia, Acute Myeloid Leukemia (AML) and Myelodysplastic Syndrome (MDS), or Chronic myelomonocytic leukemia (CMML) - weight is at least 35 kgs (77 pounds) - available mismatched related (haploidentical) or unrelated donors for peripheral blood stem cell (PBSC) donation - study staff will review additional inclusion and exclusion criteria

Exclusion Criteria:

- prior allogeneic bone marrow, peripheral blood, or cord blood HSCT - HIV positive, positive hepatitis-B surface antigen or positive hepatitis-C antibody (unless treated) - women who are pregnant, breast feeding or aim to become pregnant during the study period

Conditions & Interventions

Conditions:
Cancer
Keywords:
blood cancer, hematopoietic stem cell transplantation (HSCT)

More Information

Description: This study will enroll patients with a blood cancer who need to undergo a stem cell (bone marrow) transplant using a donor that is not a full DNA match with them. It tests TRX103, a cellular therapy, to see if it is an effective and safe way to prevent Graft versus Host Disease (GvHD), a common and potentially serious side effect of stem cell transplant.
Study Contact: Mark Juckett - juck0001@umn.edu
Principal Investigator: Mark Juckett
IRB Number: STUDY00021552