2020IS043; MT2020-06; A PHASE 1/2 STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND EFFICACY OF JSP191 FOR HEMATOPOIETIC CELL TRANSPLANTATION CONDITIONING TO ACHIEVE ENGRAFTMENT AND IMMUNE RECONSTITUTION IN SUBJECTS WITH SCID

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- at least 3 months old - diagnosis of typical Severe Combined Immunodeficiency (SCID) - patient with human leukocyte antigen (HLA) matched related or unrelated donors

Exclusion Criteria:

- acute or uncontrolled infections - patients receiving any other investigational agents, or concurrent biological, chemotherapy, or radiation therapy - patients with active malignancies - active Graft-versus-host disease (GVHD) within 6 months prior to enrollment, or on immunosuppressive therapy for GVHD

Conditions & Interventions

Interventions:
Biological: Humanized anti-CD117 Monoclonal Antibody (JSP191)
Conditions:
Immune Diseases, Rare Diseases
Keywords:
SCID, Severe combined immunodeficiency

More Information

Description: This study is looking at whether giving a new type of experimental medicine, called JSP191, can prepare the body to help the stem cell transplant work better, so the immune system can grow and fight infections. The study doctor and Sponsor also want to see how safe and well tolerated this experimental medicine is. They will study whether it is safe to give to patients and look at how much medication to give and what side effects may occur. During this study, the optimal dose of JSP191 will be determined and additional patients will be enrolled in this study using that dose level.
Study Contact: Amanda Simmons - simmo743@umn.edu
Principal Investigator: Christen Ebens
Phase: PHASE1
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