Donor-Derived Viral Specific T-cells (VSTs)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 month(s) and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Recipient must be at least 21 days after stem cell infusion
- Clinical status must allow tapering of steroids to 0.5mg/kg prednisone or other steroid equivalent
- Recipient must have achieved engraftment with ANC ≥ 500

Exclusion Criteria:

- Active acute GVHD grades II-IV
- Uncontrolled bacterial or fungal infection
- Uncontrolled relapse of malignancy requiring treatment with chemotherapy
- Infusion of ATG or alemtuzumab within 2 weeks of VST infusion

Conditions & Interventions

Interventions:
BIOLOGICAL: Viral specific VST Infusion
Conditions:
Allogeneic Stem Cell Transplant, Viral Infection, Viral Reactivation
Keywords:
Epstein-Barr Virus (EBV), Adenovirus (ADV), t-cells, donor, transplant, children, cytomegalovirus (CMV), BK virus (BKV)

More Information

Description:
In this research study, the investigators want to learn more about the use of donor-derived viral specific T-cells (VSTs) to treat viral infections that occur after allogeneic stem cell transplant. A viral specific T cell is a T lymphocyte (a type of white blood cell) that kills cells that are infected (particularly with viruses). Allogeneic means the stem cells come from another person. These VSTs are cells specially designed to fight the virus infections that can happen after a bone marrow transplant. The investigators are asking people who have undergone or will undergo an allogeneic stem cell transplant to enroll in this research study, because viral infections are a common problem after allogeneic stem cell transplant and can cause significant complications including death. Stem cell transplant reduces a person's ability to fight infections. There is an increased risk of getting new viral infections or reactivation of viral infections that the patient has had in the past, such as cytomegalovirus (CMV), Epstein-Barr virus (EBV), adenovirus (ADV), BK virus (BKV), and JC virus. There are anti-viral medicines available to treat these infections, though not all patients will respond to the standard treatments. Moreover, treatment of viral infections is expensive and time consuming, with families often administering prolonged treatments with intravenous anti-viral medications, or patients requiring prolonged admissions to the hospital. The medicines can also have side effects like damage to the kidneys or reduction in the blood counts, so in this study the investigators are trying to find an easier way to treat these infections.

Contact(s): Jamie Wilhelm - Jamie.Wilhelm@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE1
IRB Number:
System ID: NCT02048332