

## Trial of Scheduled Versus Treatment Administration of Donor-Derived Viral Specific T-cells for Viral Infections After Stem Cell Transplant

Status: RECRUITING

### Eligibility Criteria

Sex: ALL

Age:

Healthy Volunteers: This study is NOT accepting healthy volunteers

SCHEDULED ARM:

Inclusion Criteria:

- Recipient must be at least 21 days after stem cell infusion
- Clinical status must allow tapering of any steroids to < 0.5mg/kg prednisone or other steroid equivalent
- No critical illness making VST infusion hazardous

Exclusion Criteria:

- Active acute GVHD grades II-IV.
- Uncontrolled relapse of malignancy.
- Infusion of ATG or alemtuzumab within 2 weeks prior to VST infusion. Alemtuzumab levels will be collected in the second week following stem cell infusion in patients who received alemtuzumab as part of their conditioning regimen. The level must be less than or equal to 0.15 prior to infusion of VSTs. In patients with level greater than 0.15, alemtuzumab levels can be checked serially until a level  $\leq 0.15$  is obtained. They would become eligible for scheduled VST infusion at that point.

TREATMENT ARM

Inclusion Criteria:

- Blood adenovirus PCR  $\geq 1,000$
- Blood CMV PCR  $\geq 500$
- Blood EBV PCR  $\geq 9,000$
- Plasma BKV PCR  $> 1,000$
- Evidence of invasive adenovirus infection. Adenovirus infection will be defined as the presence of adenoviral positivity as detected by PCR or culture from one site such as stool or blood or urine or nasopharynx. Adenovirus disease will be defined as the presence of adenoviral positivity as detected by culture or PCR from more than 2 sites such as stool or blood or urine or nasopharynx.
- Evidence of invasive CMV infection, defined as pneumonitis, retinitis, colitis, hepatitis
- Evidence of EBV-associated lymphoproliferation (EBV-LPD) defined as proven EBV-LPD by biopsy or probable EBV-LPD defined as an elevated EBV DNA level in the blood associated with clinical symptoms (adenopathy or fever or masses on imaging) but without biopsy confirmation.
- Evidence of symptomatic BK virus infection, defined as hemorrhagic cystitis or BK nephropathy.
- No active acute GVHD grades II-IV
- No uncontrolled relapse of malignancy
- No infusion of ATG or alemtuzumab within 2 weeks of VST infusion.
- Clinical status must allow tapering of any steroids to < 0.5mg/kg prednisone or other steroid equivalent

### Conditions & Interventions

Interventions:

BIOLOGICAL: Viral Specific T-cells (VSTs) Scheduled, BIOLOGICAL: Viral Specific T-cells (VSTs) Treatment

Conditions:

Allogeneic Stem Cell Transplant, Viral Infection

### More Information

Description:

The purpose of this research study is to learn more about the use of viral specific T-lymphocytes (VSTs) to prevent or treat viral infections that may happen after allogeneic stem cell transplant. Allogeneic means the stem cells come from another person. VSTs are cells specially designed to fight viral infections that may happen after a stem cell transplant (SCT). Stem cell transplant reduces the body's ability to fight infections. Viral infections are a common problem after transplant and can cause significant complications. 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 a better way to treat these infections.

Contact(s): Celeste Dourson - celeste.dourson@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: PHASE2

IRB Number:

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