

TETRAVI Multivirus CTL for Treatment of EBV, CMV, Adenovirus, and BK Infections Post Allogeneic SCT.

NCT04013802

Status	RECRUITING
Phase	Phase 1
Sponsor	Baylor College of Medicine
Enrollment	47 participants

Key Eligibility Criteria

Inclusion (29)

- Prior myeloablative or non-myeloablative allogeneic hematopoietic stem cell transplant using either bone marrow or peripheral blood stem cells or single or double cord blood.
 - Or Received CAR-T cells targeting an antigen expressed on normal virus specific T cells
 - Treatment for Infection/Disease will fall into one of 3 categories (options):
 - Option 1: Persistent, increasing or recurrent infections despite 7 days of standard therapy;
 - a. CMV: Treatment of persistent or relapsed CMV disease or infection after standard therapy. For CMV infection, standard therapy is defined as antiviral therapy with ganciclovir, foscarnet, letermovir or cidofovir. 56, 57
- ... and 24 more (see full listing online)

Exclusion (7)

- Patients receiving ATG, Campath or other immunosuppressive T cell monoclonal antibodies within 28 days of screening for enrollment.
 - Patients with other uncontrolled infections. For bacterial infections, patients must be receiving definitive therapy and have no signs of progressing infection for 72 hours prior to enrollment. For fungal infections patients must be receiving definitive systemic anti-fungal therapy and have no signs of progressing infection for 1 week prior to enrollment.
 - Progressing infection is defined as hemodynamic instability attributable to sepsis or new symptoms, worsening physical signs or radiographic findings attributable to infection. Persisting fever without other signs or symptoms will not be interpreted as progressing infection.
 - Patients who are less than 28 days removed from their allogeneic hematopoietic stem cell transplant or who have received donor lymphocyte infusions (DLI) or CAR-T within 28 days.
 - Patients with active acute GVHD grades II-IV.
- ... and 2 more (see full listing online)

Locations (2 total)

Houston Methodist Hospital, Houston, Texas, United States
Texas Children's Hospital, Houston, Texas, United States

<https://clinicaltrials.gov/study/NCT04013802>

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