

Treatment of Refractory BK Infections With Related Donor BK Specific Cytotoxic T-cells (CTLs)

NCT04197596

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	New York Medical College
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (6)

- Patients with refractory BK infection post allogeneic HSCT, post solid organ transplantation or with primary immunodeficiencies with either
- Increasing urine and/or plasma BK RT-PCR DNA (by 1 log) after 7 days or persistent quantitative qRT-PCR DNA copies after 14 days despite two weeks of appropriate anti-viral therapy AND/OR
- Medical intolerance to anti-viral therapies including:
- renal toxicity with cidofovir or other \geq grade 2 toxicities secondary to cidofovir And/or
- known resistance to cidofovir 1.2. Consent: Written informed consent given (by patient or legal representative) prior to any study-related procedures.

... and 1 more (see full listing online)

Exclusion (12)

- Patient with acute GVHD \geq grade 2 or extensive chronic GVHD at the time of BK CTL infusion
- Patient receiving steroids (\geq 0.5 mg/kg prednisone equivalent) at the time of BK CTL infusion
- Patient treated with donor lymphocyte infusion (DLI) within 4 weeks prior to BK CTL infusion
- Thymoglobulin (ATG) or Alemtuzumab within 30 days
- Patient with poor performance status determined by Karnofsky (patients \geq 16 years) or Lansky (patients \geq 16 years) score \geq 30%

... and 7 more (see full listing online)

Locations (8 total)

University of California San Francisco, San Francisco, California, United States

Children's Hospital of Colorado, Aurora, Colorado, United States

Johns Hopkins, Baltimore, Maryland, United States

... and 5 more locations