

Cytotoxic T Lymphocytes in Treating Patients With Malignancies With BK and/or JC Virus

NCT02479698

Status	RECRUITING
Phase	Phase 2
Sponsor	M.D. Anderson Cancer Center
Enrollment	100 participants

Plain Language Summary

This study is testing specially engineered immune cells (called cytotoxic T lymphocytes, or CTLs) as a treatment for patients who have serious viral infections caused by BK virus or JC virus — viruses that can cause severe kidney damage or brain infection in people with weakened immune systems, certain cancers, or organ transplants.

****You may be eligible if...****

- You are 2 years of age or older
- You have a weakened immune system (such as from a transplant, HIV/AIDS, or cancer treatment), OR you have JC virus brain infection (called PML), OR you have Merkel cell cancer
- Blood or urine tests confirm a BK or JC virus infection, or kidney inflammation due to BK virus
- Your current antiviral medications have not worked
- You are able to reduce steroid medications to a low dose
- Women of childbearing age must have a negative pregnancy test and agree to use contraception

****You may NOT be eligible if...****

- You are currently on high-dose steroids
- You received certain powerful immune-suppressing treatments very recently
- You have other active, uncontrolled infections (beyond HIV)
- You have severe acute graft-versus-host disease (grades II to IV) after a bone marrow transplant

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (9)

- Patients ≥ 2 years. English and non-English speaking patients are eligible.
- Immunocompromised patients; and/or Non-immunocompromised patients with PML/JC virus Encephalitis; and/or patients with any type of malignancies; and/or HIV/AIDS; and/or history of solid organ transplant; and/or Merkel polyoma-virus related Merkel cell tumor(s) with measurable disease on imaging per RECIST criteria.
- Patients with microscopic hematuria OR biopsy proven BK nephritis and urine or blood PCR positive for BK virus and/or JC viral encephalitis and/or JC end-organ disease and/or polyomavirus.
- Clinical status at enrollment to allow tapering of steroids to less than 0.5 mg/kg/day of prednisone.
- Patients who are currently receiving treatment with cidofovir, leflunomide, or other antiviral therapy with no response, will be eligible for CTL infusion.

... and 4 more (see full listing online)

Exclusion (3)

- Patients receiving prednisone \geq 0.5 mg/kg/day at time of enrollment, or have received ATG within 14 days or have received donor lymphocyte infusion (DLI) or Campath within 28 days of enrollment.

[Patients with other uncontrolled infections \(except HIV/AIDS\). 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](#)
DISCLAIMER: This information is provided for informational purposes only and does not constitute medical advice. Always consult a qualified healthcare professional for clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.

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 with active acute (GVHD) grades II-IV

Locations (1 total)

M D Anderson Cancer Center, Houston, Texas, United States