

Virus Specific Cytotoxic T-Lymphocytes (CTLs) for Refractory Cytomegalovirus (CMV)

NCT03266640

Status	RECRUITING
Phase	Phase 2
Sponsor	New York Medical College
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (12)

- Patients with refractory CMV infection post allogeneic HSCT, with primary immunodeficiencies or post solid organ transplant with either
- Increasing or persistent quantitative qRT-PCR DNA copies despite two weeks of appropriate anti-viral therapy AND/OR
- Medical intolerance to anti-viral therapies including:
- ANC $< 500/mm^2$ secondary to ganciclovir
- renal toxicity with foscarnet And/or
- ... and 7 more (see full listing online)

Exclusion (5)

- A patient meeting any of the following criteria is not eligible for the present study:
- Patient with acute GVHD $>$ grade 2 or extensive chronic GVHD at the time of CMV CTL infusion Patient receiving steroids (>0.5 mg/kg prednisone equivalent) at the time of CMV CTL infusion Patient treated with donor lymphocyte infusion (DLI) within 4 weeks prior to CMV CTL infusion Thymoglobulin (ATG), Alemtuzumab or T cell immunosuppressive monoclonal antibodies within 30 days Patient with poor performance status determined by Karnofsky (patients >16 years) or Lansky (patients ≤ 16 years) score $\leq 30\%$ CMV retinitis Concomitant enrollment in another experimental clinical trial investigating the treatment of refractory CMV infection.
- Any medical condition which could compromise participation in the study according to the investigator's assessment Known HIV infection Female patient of childbearing age who is pregnant or breast-feeding or not willing to use an effective method of birth control during study treatment.
- Known hypersensitivity to iron dextran Patients unwilling or unable to comply with the protocol or unable to give informed consent.
- Known human anti-mouse antibodies CMV retinitis, meningitis, encephalitis, and/or cerebritis

Locations (9 total)

Children's Hospital Los Angeles, Los Angeles, California, United States
University of California San Francisco, San Francisco, California, United States
Indiana University, Indianapolis, Indiana, United States
... and 6 more locations

<https://clinicaltrials.gov/study/NCT03266640>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).