Adenovirus-specific Cytotoxic T-lymphocytes for Refractory Adenovirus Infection

NCT03266627

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

Key Eligibility Criteria

Inclusion (11)

- Patients with Adenovirus infections post allogeneic HSCT, with primary immunodeficiencies or post solid organ transplant with:
- Increasing or persistent quantitative ADV RT-PCR DNA copies despite two weeks of appropriate anti-viral therapy and/or
- clinical symptoms attributed to adenovirus, including pneumonitis, hemorrhagic cystitis, colitis, hepatitis AND/OR
- Medical intolerance to anti-viral therapies including:
- grade 2 renal insufficiency secondary to cidofovir Consent: Written informed consent given (by patient or legal representative) prior to any study-related procedures.

... and 6 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 CTL infusion Patient receiving steroids (\>0.5 mg/kg prednisone equivalent) at the time of CTL infusion Patient treated with donor lymphocyte infusion (DLI) within 4 weeks prior to CTL infusion Patient with poor performance status determined by Karnofsky (patients \>16 years) or Lansky (patients d16 years) score d30% Concomitant enrollment in another experimental clinical trial investigating the treatment of refractory adenovirus infection(s) 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
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Locations (10 total)

Children's Hospital Los Angeles, Los Angeles, California, United States
University of California San Francisco, San Francisco, California, United States
Children's Hospital of Colorado, Aurora, Colorado, United States
... and 7 more locations