

Viral Specific T-Lymphocytes to Treat Infection With Adenovirus, Cytomegalovirus or Epstein-Barr Virus in Patients With Compromised Immunity

NCT06909110

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Jessie L. Alexander
Enrollment	25 participants

Key Eligibility Criteria

Inclusion (31)

- Patient, parent, or legal guardian must have given written informed consent, according to FDA guidelines. For patients ≥ 7 years of age who are developmentally able, assent or affirmation will be obtained, if feasible.
- Male or female, 1 month through 65 years old, inclusive, at the time of informed consent.
- Prior allogeneic hematopoietic stem cell transplant, AND/OR prior solid organ transplant (liver, kidney, lung and/or heart, intestinal, pancreatic, and/or multivisceral), AND/OR diagnosis of primary immunodeficiency AND/OR current/recent administration of immunosuppressive therapy for cancer or autoimmune disease.
- If receiving steroids, must be able to taper dose to less than 1 mg/kg/day prednisone (or equivalent) prior to cellular infusion.
- Negative pregnancy test for females ≥ 10 years old or who have reached menarche, unless surgically sterilized or post-menopausal.

... and 26 more (see full listing online)

Exclusion (13)

- Received ATG or Alemtuzumab within 21 days of viral-specific T cell infusion and a lack of evidence of T cell survival, defined by <10 CD3+ T cells/uL (in unique situations, plasmapheresis may be considered).
- Active acute GVHD grades II-IV.
- Active severe chronic GVHD.
- Received donor lymphocyte infusion, with the exception of a fraction of an umbilical cord blood, within 21 days of planned viral-specific T cell infusion. Subjects receiving a fraction of an umbilical cord blood within 21 days of the viral-specific T cell infusion will not be excluded.
- Active and uncontrolled relapse of malignancy (other than EBV+ post-transplant lymphoproliferative disorder or lymphoma).

... and 8 more (see full listing online)

Locations (3 total)

Jessie Alexander, Palo Alto, California, United States
Lucile Packard Children's Hospital, Palo Alto, California, United States
Lucile Packard Children's Hospital, Palo Alto, California, United States

<https://clinicaltrials.gov/study/NCT06909110>

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