

Pilot Study of Haploidentical Donor Adenovirus Specific T-lymphocytes to Treat Refractory Adenovirus Infections

NCT04722029

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Nationwide Children's Hospital
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (13)

- Age 0 days to 60 years with one of the following conditions:
 - Patients who are solid organ transplantation recipients (renal, heart, lung, liver, pancreas, small bowel, multi-visceral) and are > 28 days post-transplant at the time of screening.
 - Patients with underlying malignancy who are receiving or have received chemotherapy within 6 months of screening.
 - Patients with known autoimmune or autoinflammatory conditions, not associated with a known underlying primary immunodeficiency
 - Patients who are receiving or have received systemic immunosuppressive therapies in the 30 days prior to screening including: biologic agents, calcineurin inhibitors, mTOR inhibitors, or corticosteroid
- ... and 8 more (see full listing online)

Exclusion (16)

- Receipt of anti-thymocyte globulin (ATG), alemtuzumab, cytoxan, or other T-cell depleting drugs or monoclonal antibodies within 28 days from enrollment
 - Receiving corticosteroid (prednisone equivalent) e 0.5mg/kg/day or e 20mg/day at the time of enrollment
 - Recipients of allogeneic hematopoietic stem cell transplant (bone marrow, peripheral blood or umbilical cord blood)
 - Evidence of uncontrolled infection (except ADV) as follows:
 - Bacterial infections - patients must be receiving definitive therapy and have no signs of progressing infection for 72 hours prior to enrollment
- ... and 11 more (see full listing online)

Locations (1 total)

Nationwide Children's Hospital, Columbus, Ohio, United States