

Adoptive T Lymphocyte Administration for Chronic Norovirus Treatment in Immunocompromised Hosts

NCT04691622

Status	RECRUITING
Phase	Phase 1
Sponsor	Children's National Research Institute
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (38)

- Participants must meet one of the following criteria:
- Recipient of prior myeloablative or non-myeloablative allogeneic hematopoietic stem cell transplant using either bone marrow or peripheral blood stem cells or single or double cord blood OR
- Primary immunodeficiency disorder (as defined by clinical and laboratory evaluations)⁸¹ and have not undergone HSCT, OR
- Recipients of solid organ transplant.
- Documentation of chronic norovirus infection:
... and 33 more (see full listing online)

Exclusion (23)

- Participants receiving biological or immunosuppressive monoclonal antibodies targeting T cells within 28 days prior to NST infusion, including ATG, Alemtuzumab, Basiliximab, Tocilizumab, Brentuximab, or other medications under this category as determined by the investigators.
- a) If alemtuzumab has been received within 6 weeks prior to NST infusion, plasma levels should be obtained to ensure drug clearance (d0.16 pg/ml).
- Participants who have received donor lymphocyte infusion (DLI), chimeric antigen receptor T cell infusion, or other experimental cellular therapies within 28 days prior to NST infusion.
- Participants with SCID who have undergone \pm TCR depleted HSCT within the past 100 days post-transplant.
- Participants who have received ruxolitinib or other JAK inhibitors within 7 days prior to NST infusion.
... and 18 more (see full listing online)

Locations (3 total)

Children's National Hospital, Washington D.C., District of Columbia, United States
Johns Hopkins University, Baltimore, Maryland, United States
National Institutes of Health (NIH), Bethesda, Maryland, United States