A Single-arm, Dose-escalation Trial of Long-acting Recombinant Human IL-7 (NT-I7, Efineptakin Alfa) for Idiopathic CD4 Lymphopenia

NCT05600920

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (11)

- Individuals must meet all of the following criteria to be eligible for study participation:
- Aged 18 to 75 years.
- Able to provide informed consent.
- Co-enrolled in NIH protocol 09-I-0102, Etiology, Pathogenesis, and Natural History of Idiopathic CD4+ Lymphocytopenia (EPIC) study (NCT0086726).
- Documented ICL, defined as CD4 T-cell count \<300 cells/microliter in at least 2 different measurements at least 6 weeks apart, at any point in the past.

... and 6 more (see full listing online)

Exclusion (12)

- Individuals meeting any of the following criteria will be excluded from study participation:
- Current moderate or severe acute illness (eg, febrile illness, seizure, myocardial infarction, cerebrovascular accident, pulmonary embolism) that in the opinion of the study team would make the individual unsuitable for the study.
- Clinical or microbiologic evidence of active progressive cryptococcal central nervous system (CNS) disease or nontuberculous mycobacterial (NTM) infections within the last year. History of stable cryptococcal CNS disease or NTM diseases since more than 1 year can be enrolled but will need to have undetectable CSF cryptococcal antigen and initiate/maintain antifungal or antimycobacterial treatment, respectively.
- Pregnant or breastfeeding.
- HIV infection, chronic hepatitis B or C infection, and any other recognized congenital or acquired immunodeficiency (eg, SCID IL-2/JAK3/ADA, MAGT1, MHC1 deficiency, CVID, DOCK8).

... and 7 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States