

Safety of Belimumab in People With Idiopathic CD4 Lymphopenia and Autoantibodies (Phoebe)

NCT04097561

Status	RECRUITING
Phase	Phase 1
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (15)

- Individuals must meet all of the following criteria to be eligible for study participation:
- Aged 18-70 years.
- Enrolled in study 09-I-0102.
- Has a documented diagnosis of ICL, defined as the following:
- CD4 count $<$ 300 cells/microliter in at least 2 separate measurements 6 weeks apart at any point in the past, AND ... and 10 more (see full listing online)

Exclusion (20)

- Individuals meeting any of the following criteria will be excluded from study participation:
- Prior receipt of belimumab for any reason.
- Allergy to any component of belimumab formulation.
- HIV infection or other recognized congenital or acquired immunodeficiency.
- Current moderate or severe acute illness (eg, febrile illness, seizure, myocardial infarction, cerebrovascular accident, pulmonary embolism) or progressive serious infection related to ICL that, in the opinion of the principal investigator, would make the participant unsuitable for the study. Pre-existing infections that have been stable both clinically and with laboratory (eg, cryptococcal antigen titer or histoplasma antigen level) and radiographic evaluations on maintenance therapy over at least a year will be eligible. ... and 15 more (see full listing online)

Locations (1 total)

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