

Study of the ITK Inhibitor Soquelitinib to Reduce Lymphoproliferation and Improve Cytopenias in Autoimmune Lymphoproliferative Syndrome (ALPS)-FAS Patients

NCT06730126

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (11)

- To be eligible to participate in this study, an individual must meet all the following criteria:
 - Aged ≥ 16 years.
 - Able to provide informed consent (for ages ≥ 18 years) or has a parent(s) or guardian(s) who can provide permission to participate on their behalf (for ages <18 years).
 - Has a documented diagnosis of ALPS-FAS.
 - Has clinical evidence of active disease, defined as at least one enlarged lymph node and/or enlarged spleen.
- ... and 6 more (see full listing online)

Exclusion (16)

- An individual who meets any of the following criteria will be excluded from participation in this study:
 - Profound grade 3 or 4 cytopenias that cannot be improved with immunomodulatory treatments prior to enrolling in the clinical trial and starting the study drug. Per investigator discretion, individuals on a single agent may be included if the dose is stable for 12 weeks at screening and is not expected to confer additive toxicity.
 - Renal impairment, defined as serum creatinine >1.5 mg/dL (or 133 micromol/L) or estimated glomerular filtration rate <60 mL/min/1.73 m².
 - Liver impairment, defined as bilirubin, alanine aminotransferase, or aspartate aminotransferase greater than 2.5 times the upper limit of normal.
 - History of EBV-associated lymphoma.
- ... and 11 more (see full listing online)

Locations (3 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States
The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, United States
Texas Children's Hospital, Houston, Texas, United States

<https://clinicaltrials.gov/study/NCT06730126>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.