Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Fx-5A in Healthy Volunteers

NCT04216342

Status	RECRUITING
Phase	Phase 1
Sponsor	National Heart, Lung, and Blood Institute (NHLBI)
Enrollment	64 participants

Key Eligibility Criteria

Inclusion (4)

- years of age or above
- Women of childbearing potential must be willing to use an appropriate form of birth control during the course of the study and two forms of birth control during the interventional portion of the study and up to day 7 after infusion
- Subject willing to return for all study visits, complete all study-related tasks, and agree not to participate in other research studies from screening visit to study completion
- Willingness and capacity to provide written informed consent

Exclusion (12)

- Pregnancy, planned pregnancy (within the study period), or current breastfeeding
- Subject taking any supplements or medications for at least 8 weeks prior to enrollment (with the exception of oral contraceptives).
- Known allergies or intolerances to any components of the Fx-5A peptide-lipid complex
- Known allergies or intolerances to eggs or egg components
- History of febrile illness within 5 days prior to dosing

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

Locations (1 total)

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