PK and PD Study of NPI-001 and Cysteamine Bitartrate

NCT05994534

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Nacuity Pharmaceuticals, Inc.
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (4)

- Males or females, any race, e 10 years of age.
- Diagnosis of nephropathic cystinosis and able to cease cysteamine therapy for 2 days.
- Females will be nonpregnant and nonlactating, and females of childbearing potential and males will agree to use contraception as detailed in the protocol.
- Able to comprehend and willing to sign an informed consent /assent form and to abide by the study restrictions (travel as necessary, clinical phase 1 unit or similar for up to 3 days).

Exclusion (6)

- Have undergone kidney transplantation.
- Are receiving dialysis treatment.
- History of significant hypersensitivity to NAC or any ingredient of NPI-001 oral solution.
- Participation in a clinical study involving administration of an investigational drug (new chemical entity) in the 30 days prior to Day 1.
- Inability to provide blood samples, including difficulty with venous access.

... and 1 more (see full listing online)

Locations (1 total)

Children's Hospital at Westmead, Westmead, New South Wales, Australia