Ascending Doses of Crofelemer Powder for Oral Solution in Pediatric Microvillus Inclusion Disease (MVID)

NCT06721871

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

Key Eligibility Criteria

Inclusion (8)

- Participants (assent for participants older than 7 years of age) and/or their legal parent/guardian sign an Informed Consent Form (ICF) indicating that they understand the purpose of the procedures required for the study and are willing to participate
- When appropriate, pediatric participants, whose age, cognitive skills, reading abilities and maturity allow the understanding of the study protocol should provide written assent to participate.
- Male or female participants between the ages of 3 months to 17 years at the time of signing the informed consent or providing assent
- Have a confirmed diagnosis (genetic and/or histologic) of MVID
- Are able to ingest reconstituted Crofelemer Powder for Oral Solution either orally (PO) or through a previously-placed G-tube or GJ-Tube (not via J-Tube)

... and 3 more (see full listing online)

Exclusion (11)

- Within the last 4 weeks before study initiation, participants have:
- had significant changes to PS requirements (i.e., ± \> 20%)
- had a new requirement for diuretics
- had any infection requiring IV antibiotic administration
- had a documented active gastrointestinal infection

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

Locations (3 total)

Boston Children's Hospital, Boston, Massachusetts, United States
UOS Gastroenterolgia e Riabilitazione nutrizionale Piazza Sant' Onofrio 4, Rome, Italy
Al Jalila Children's Hospital, Dubai, United Arab Emirates