

Study of Choline Chloride for Injection in Adolescent and Adult Patients With Intestinal Failure Receiving Long Term Parenteral Support

NCT06910943

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Protara Therapeutics
Enrollment	129 participants

Key Eligibility Criteria

Inclusion (4)

- Male or female 12 years of age or older at the time of signing the informed consent
- Individuals who have voluntarily given written informed consent after the nature of the study has been explained according to applicable requirements, prior to study entry
- Individuals with intestinal failure receiving long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated who are receiving stable PS at time of screening and for the duration of the study; Note: Long-Term PS = Participant must have been receiving PS for at least 6 months prior to screening and requiring PS at least 3 times per week
- Females of childbearing potential must have a negative urine pregnancy test at screening

Exclusion (8)

- Patients taking steatogenic medications for e 12 weeks in the past 12 months; those taking any medicine that could affect the measurement of hepatic steatosis within 12 weeks prior to study entry
- Evidence of systemic active infection at the time of dosing
- Participants intending to take non-study drug choline supplements or choline-containing multivitamins during the course of the study
- Participants unwilling to limit alcohol intake to no more than 20/g a day for 24 hours prior to their screening visit and for the duration of the study
- Active malignancy (excluding basal cell skin tumor, low or very low risk prostate cancer, cervical carcinoma in situ and local resected cervical cancer)

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

Locations (14 total)

University of Colorado School of Medicine, Aurora, Colorado, United States
Columbia University Medical Center/ New York Presbyterian Hospital, New York, New York, United States
Duke Clinic - Abdominal Transplant Research Office, Durham, North Carolina, United States
... and 11 more locations

<https://clinicaltrials.gov/study/NCT06910943>

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