

Safety and Efficacy Study of Intracystic TARA-002 for the Treatment of Lymphatic Malformations in Participants 6 Months to Less Than 18 Years of Age

NCT05871970

Status	RECRUITING
Phase	Phase 2
Sponsor	Protara Therapeutics
Enrollment	38 participants

Key Eligibility Criteria

Inclusion (4)

- Male or female participants 6 months to less than 18 years of age at the time of informed consent/assent form was signed
- Participants whose parent/LAR(s) have voluntarily given written consent and participants who provided assent (if applicable) after the study has been explained to them
- Participants with macrocystic LM or mixed cystic LM (e 50% macrocystic disease measured by volume) of the Head/Neck/Mediastinum according to the ISSVA 2018 criteria (ISSVA 2018) measured via LM imaging at Screening to confirm, upon central review, the diagnosis of macrocystic or mixed cystic LM
- Participants who may have had surgical or sclerotherapy treatment for their LM, but not within six months of the consent/assent form being signed

Exclusion (5)

- Penicillin allergy
- Vascular tumors or combined vascular malformations
- Microcystic LM or mixed cystic LM with predominant microcystic features
- LMs of the orbit (orbital LM) as target cyst
- For more information on eligibility criteria, please contact the sponsor.

Locations (10 total)

Children's Hospital of Alabama, Birmingham, Alabama, United States
Arkansas Children's Hospital/UAMS, Little Rock, Arkansas, United States
Children's Hospital of Colorado, Aurora, Colorado, United States
... and 7 more locations