

Alpelisib in Pediatric and Adult Patients With Lymphatic Malformations Associated With a PIK3CA Mutation.

NCT05948943

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	232 participants

Key Eligibility Criteria

Inclusion (7)

- Signed informed consent and assent (when applicable) from the participant, parent, legal authorized representative or guardian.
- Participant must be willing to remain at the clinical site as required by the protocol and be willing to adhere to study restrictions and examination schedules.
- Participant has a physician confirmed and documented diagnosis of a symptomatic LyM at the time of informed consent (Note: the physician must confirm that the LyM cannot be included under the PROS diagnostic criteria).
- Participant is not considered as a candidate for or is not willing to receive non-drug therapies including but not limited to sclerotherapy, embolization, and surgery until the completion of Week 24 in Stage 1 and 2.
- Participant has evidence of a somatic mutation(s) in the PIK3CA gene prior to randomization.

... and 2 more (see full listing online)

Exclusion (5)

- Participant has a physician-confirmed and documented diagnosis of PROS at the time of informed consent.
- Participant has a physician-confirmed and documented diagnosis of a Central Conducting Lymphatic Anomaly, General Lymphatic Anomaly, Gorham-Stout disease, Kaposiform lymphangiomatosis at the time of informed consent.
- Participant has a known history of Stevens-Johnson syndrome, erythema multiforme, or toxic epidermal necrolysis at the time of informed consent.
- Participant has an established diagnosis of type I diabetes mellitus or uncontrolled type II diabetes mellitus at the time of informed consent.
- Participant had previous treatment with alpelisib and/or any other PI3K inhibitors with treatment duration longer than 2 weeks at the time of informed consent.

Locations (49 total)

UCSF Benioff Children s Hospital, Oakland, California, United States
Lucile Packard Childrens Hosp, Palo Alto, California, United States
Childrens National Medical Center, Washington D.C., District of Columbia, United States
... and 46 more locations

<https://clinicaltrials.gov/study/NCT05948943>

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