

A Study to Evaluate the Effect of Aficamten in Pediatric Patients With Symptomatic Obstructive Hypertrophic Cardiomyopathy (oHCM).

NCT06412666

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Cytokinetics
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (17)

- Period 1: Treatment Period
 - Males and females between 12 and < 18 years of age at screening and at Day 1.
 - Body weight \geq 45 kg for the initial cohort and then body weight \geq 35 kg after at least 10 participants in the initial cohort have undergone dose titration up to Week 4 without observed events of LVEF < 50% at the starting dose of 5 mg qd.
 - Core laboratory confirmation of the following oHCM echocardiographic criteria at screening:
 - Left ventricular (LV) hypertrophy with nondilated LV chamber in the absence of other cardiac disease.
- ... and 12 more (see full listing online)

Exclusion (17)

- Period 1: Treatment Period
 - Any of the following criteria will exclude potential participants from the trial:
 - Significant valvular heart disease.
 - Moderate or severe valvular aortic stenosis or fixed subaortic obstruction.
 - Mitral regurgitation that is greater than mild in severity and not due to systolic anterior motion of the mitral valve (per judgment of Principal Investigator or designee).
- ... and 12 more (see full listing online)

Locations (38 total)

Phoenix Children's Hospital, Phoenix, Arizona, United States
Children's Hospital Los Angeles, Los Angeles, California, United States
University of California, Los Angeles (UCLA), Los Angeles, California, United States
... and 35 more locations