

A Study of Mavacamten in Adults With Obstructive Hypertrophic Cardiomyopathy in India (ROVER)

NCT07004972

Status	RECRUITING
Phase	Phase 4
Sponsor	Bristol-Myers Squibb
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (8)

- Diagnosed with obstructive hypertrophic cardiomyopathy (HCM) consistent with current American College of Cardiology Foundation/American Heart Association and European Society of Cardiology guidelines.
- Has unexplained LV hypertrophy with nondilated ventricular chambers in the absence of other cardiac (ie, hypertension, aortic stenosis) or systemic disease and with maximal LV wall thickness \leq 15 mm (or \leq 13 mm with positive family history of hypertrophic cardiomyopathy).
- Has LVOT (Valsalva left ventricular outflow tract) peak gradient \leq 50 mmHg during screening as assessed by TTE at rest, Valsalva maneuver, or post exercise LVOT peak gradient.
- Has LVOT peak gradient with Valsalva at screening TTE of \leq 30 mmHg.
- Has adequate acoustic windows to enable accurate TTEs.

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

Exclusion (6)

- Known infiltrative or storage disorder causing cardiac hypertrophy that mimics obstructive hypertrophic cardiomyopathy, such as Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy.
- Has paroxysmal atrial fibrillation present per the investigator's evaluation of the participant's ECG at the time of screening.
- Has persistent or permanent atrial fibrillation not on anticoagulation for at least 4 weeks prior to screening and/or not adequately rate controlled within 6 months prior to screening. (Note: Participants with persistent or permanent atrial fibrillation who are anticoagulated and adequately rate-controlled are allowed).
- Has a history of syncope with exercise within 6 months prior to screening.
- History of sustained ventricular tachyarrhythmia ($>$ 30 seconds) within 6 months prior to screening.

... and 1 more (see full listing online)

Locations (31 total)

Local Institution - 0014, Hyderabad, Andhra Pradesh, India

Local Institution - 0011, Ahmedabad, Gujarat, India

Local Institution - 0006, Surat, Gujarat, India

... and 28 more locations