A Study to Assess the Real-World Effectiveness of Mavacamten in Adult Patients With Obstructive Hypertrophic Cardiomyopathy in China

NCT07361289

Status	RECRUITING
Sponsor	Bristol-Myers Squibb
Enrollment	500 participants

Key Eligibility Criteria

Inclusion (9)

- Participants aged e 18 years (participants enrolled retrospectively: at the time of initial mavacamten prescription), irrespective of gender.
- Diagnosed with obstructive hypertrophic cardiomyopathy (HCM) consistent with current American College of Cardiology Foundation/American Heart Association, European Society of Cardiology, and Chinese guidelines for diagnosis and treatment of patients with hypertrophic cardiomyopathy, i.e., satisfy criteria below:
- Has unexplained left ventricular (LV) hypertrophy with non-dilated ventricular chambers in the absence of other cardiac (e.g., hypertension, aortic stenosis) or systemic disease and with maximal LV wall thickness e 15 mm (or e 13 mm with positive family history of hypertrophic cardiomyopathy) in the most recent medical record within 3 months prior to enrollment, and
- Peak left ventricular outflow tract (LVOT) gradient e 30 mmHg at rest or with provocation in the most recent medical record within 3 months prior to enrollment as assessed by echocardiography.
- Has documented left ventricular ejection fraction (LVEF) e 55%, as measured by resting transthoracic echocardiography (TTE) in the most recent medical record within 3 months prior to enrollment.

... and 4 more (see full listing online)

Exclusion (7)

- Known HCM phenocopy disease (e.g., Fabry disease, amyloidosis).
- Participants who are expected to undergo major cardiac surgery during the study.
- Prior treatment of obstructive HCM with invasive septal reduction (surgical myectomy or percutaneous alcohol septal ablation \[ASA\] or septal radiofrequency ablation) within 6 months prior to enrollment (participants enrolled retrospectively: within 6 months prior to initial mavacamten prescription); participants with an unsuccessful myectomy or percutaneous ASA or septal radiofrequency ablation performed \>6 months prior to enrollment (participants enrolled retrospectively: within 6 months prior to initial mavacamten prescription) may be enrolled.
- Currently treated with disopyramide or ranolazine (within 14 days prior to enrollment \[participants enrolled retrospectively: within 14 days prior to initial mavacamten prescription\]) or participants who are expected to be taking disopyramide, ranolazine, verapamil in combination with ²ŧreceptor blockers, or diltiazem in combination with ²ŧreceptor blockers during the study.
- Presence of other diseases that may affect completion of 96 weeks follow-up as assessed by the investigator.

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

Locations (15 total)

Local Institution - 0008, Beijing, Beijing Municipality, China
Peking Union Medical College Hospital, Beijing, Beijing Municipality, China
Peking University First Affiliated Hospital, Beijing, Beijing Municipality, China
... and 12 more locations