

A Clinical Study Evaluating the Replacement of the Native Mitral Valve Using the ReValve System

NCT07450911

Status	RECRUITING
Phase	Phase 1
Sponsor	ReValve Solutions Inc.
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (5)

- Symptomatic MR (e3+) due to ischemic and non-ischemic cardiomyopathy etiology determined by assessment of a qualifying transthoracic echocardiogram (TTE) obtained within 60 days and transesophageal echocardiogram (TEE) obtained within 90 days prior to subject registration, with MR severity based principally on the TTE study.
- New York Heart Association (NYHA) Functional Class II, III or ambulatory IV.
- Left Ventricular Ejection Fraction (LVEF) is e30% (within 90 days prior to subject registration, assessed by the site using any one of the following methods: echocardiography, contrast left ventriculography, gated blood pool scan or cardiac magnetic resonance imaging (MRI)).
- Age greater than 18 years
- Left Ventricular End Systolic Dimension (LVESD) is d 65 mm assessed by site based on a transthoracic echocardiographic (TTE) obtained within 90 days prior to subject consent.

Exclusion (8)

- Untreated clinically significant coronary artery disease requiring revascularization.
- Need for emergent or urgent surgery for any reason or any planned cardiac surgery within the next 12 months.
- Status 1 heart transplant or prior orthotopic heart transplantation
- Cerebrovascular accident within 30 days prior to subject's consent
- Pregnant or planning pregnancy within next 12 months.

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

Locations (3 total)

Healthycore, Tbilisi, Georgia
Tbilisi Heart and Vascular Center, Tbilisi, Georgia
Tbilisi Heart Center, Tbilisi, Georgia