

Percutaneous or Surgical Repair In Mitral Prolapse And Regurgitation for 60 Year-olds (PRIMARY)

NCT05051033

Status	RECRUITING
Phase	Not Applicable
Sponsor	Annetine Gelijns
Enrollment	450 participants

Key Eligibility Criteria

Inclusion (5)

- Adult patients e60 years with moderately-severe or severe (3+ or 4+/4+) primary degenerative (Carpentier type II) MR defined by transthoracic echocardiography
- Clinical indication for MV intervention and anatomic candidate for both surgical MV repair and transcatheter edge-to-edge repair (TEER) per local heart team assessment with central eligibility committee verification
- Patients across the surgical risk spectrum (low, intermediate, and high risk) depending on local heart team assessment and central eligibility committee verification (see ACC/AHA 2020 guidelines for the management of patients with valvular heart disease)
- Patients with AF who meet an indication for a concomitant ablation procedure be included provided the local heart team and central eligibility committee decide they are eligible for both catheter-based and surgical ablation.
- Ability to perform 6-minute walk test (6MWT) and complete Kansas City Cardiomyopathy Questionnaire (KCCQ) instrument

Exclusion (21)

- Non-degenerative types of primary MR (e.g., cleft leaflet)
- Secondary or functional MR
- Hypertrophic obstructive cardiomyopathy
- Presence of an IVC filter or permanent pacing/ICD leads that would interfere with TEER per local heart team assessment
- Known allergic reactions to intravenous contrast

... and 16 more (see full listing online)

Locations (61 total)

Keck Hospital of the University of Southern California, Los Angeles, California, United States

Cedars Sinai Medical Center, Los Angeles, California, United States

University of California San Francisco, San Francisco, California, United States

... and 58 more locations