

J-Valve Transfemoral Pivotal Study

NCT06455787

Status	RECRUITING
Phase	Not Applicable
Sponsor	JC Medical, Inc., an affiliate of Edwards Lifesciences LLC
Enrollment	194 participants

Key Eligibility Criteria

Inclusion (8)

- Symptomatic according to New York Heart Association (NYHA) functional class (FC) II or higher
 - Severe AR, defined as follows, as assessed by Imaging Core Laboratory:
 - A. Severe AR by Transthoracic Echocardiography (TTE) (grade 3 or 4)
 - B. OR, if indeterminate AR, by TTE, ANY ONE of the following:
 - i. Cardiac magnetic resonance imaging (CMR)-derived aortic regurgitant fraction (RF) $\geq 43\%$
 - ii. CMR-derived RF $\geq 33\%$ + left ventricular dilation (left ventricular end diastolic volume index [LVEDVi]) $> 105 \text{ mL/m}^2$ for men or LVEDVi $> 96 \text{ mL/m}^2$ for women)
 - iii. CMR-derived RF $\geq 33\%$ + LV ejection fraction (LVEF) $\geq 55\%$ or left ventricular end systolic volume index (LVESVi) $\geq 43 \text{ mL/m}^2$;
 - iv. Severe AR by Transesophageal Echocardiography (TEE) (grade 3 or 4)
- ... and 3 more (see full listing online)

Exclusion (41)

- Previous prosthetic aortic valve (bioprosthesis or mechanical) implant
 - Aortic valve stenosis $>$ moderate*
 - Severe mitral valve or tricuspid valve regurgitation*
 - Severe mitral valve or tricuspid valve stenosis*
 - Active infection, including infective endocarditis
- ... and 36 more (see full listing online)

Locations (37 total)

HonorHealth Research & Innovation Institute, Scottsdale, Arizona, United States
Cedars Sinai, Los Angeles, California, United States
Stanford University Medical Center, Palo Alto, California, United States
... and 34 more locations

<https://clinicaltrials.gov/study/NCT06455787>

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