

TRanscAtheter TreatMent of PurE Aortic Regurgitation With VitaFlow Liberty System

NCT06818084

Status	RECRUITING
Phase	Phase 4
Sponsor	Ruijin Hospital
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (2)

- Asymptomatic moderate-to-severe or greater isolated aortic regurgitation meeting at least one of the following criteria:
- LVEF $\geq 55\%$ (measured by biplane Simpson's method); LVESD ≤ 50 mm ; LVESDi ≤ 22 mm/mm² LVESVi ≤ 45 mL/m² Anatomical suitability for TAVR as assessed by the heart team. Provision of written informed consent by the patient or their legal guardian, with agreement to the treatment plan and willingness and ability to comply with all required follow-up assessments.

Exclusion (3)

- Life expectancy < 1 year. LVEF $< 45\%$. eGFR < 30 mL/min/1.73m². Known allergy or contraindication to required medications (e.g., aspirin, clopidogrel, warfarin) or contrast media.
- Any condition that precludes contrast-enhanced CT. Concurrent moderate-to-severe or severe valvular heart disease other than aortic regurgitation.
- Poor patient compliance, unable to complete follow-up as required. Any other condition that, in the investigator's judgment, would make the patient unsuitable for the study.

Locations (4 total)

Ruijin hospital, Shanghai JiaoTong University School of Medicine, Shanghai, Shanghai Municipality, China
Shanghai Chest Hospital, Shanghai, Shanghai Municipality, China
Zhongshan Hospital, Fudan University, Shanghai, Shanghai Municipality, China
... and 1 more locations