Safety and Feasibility Study of the MitraFix® Transcatheter Mitral Valve System

NCT07501234

Status	RECRUITING
Phase	Not Applicable
Sponsor	Mitrassist Lifesciences Limited Co., Ltd.
Enrollment	5 participants

Key Eligibility Criteria

Inclusion (5)

- Moderate to severe or severe (e3+) mitral regurgitation.
- Age e 18 years.
- Patients at high risk for traditional open-heart surgery, defined as: STS mortality risk for mitral valve replacement e 8%; OR presence of 2 or more frailty indices; OR presence of 2 or more major organ dysfunctions that cannot be improved post-operatively; OR other comorbidities or factors making them unsuitable for surgery.
- Anatomically suitable for transcatheter MitraFix® system implantation via a transfemoral-transseptal approach as assessed by the investigator; the transfemoral-transseptal access route meets the requirements of the delivery system.
- Able to understand the study purpose, voluntarily participate, sign the informed consent form, and willing to accept relevant examinations and clinical follow-ups.

Exclusion (24)

- Severe mitral stenosis.
- Severe calcification of mitral leaflets and/or annulus; anatomical structures of the mitral valve apparatus (e.g., papillary muscles) unsuitable for device implantation.
- High risk of left ventricular outflow tract obstruction (LVOTO) based on pre-operative CT/TEE planning (estimated neo-LVOT \< 150 mm²), which cannot be avoided by procedural optimization.
- Presence of previous implants in the mitral position (surgical bioprosthetic or mechanical valves, surgical annuloplasty rings, etc.).
- Infective endocarditis or evidence of active infection.

... and 19 more (see full listing online)

Locations (1 total)

Fuwai Hospital, Chinese Academy of Medical Sciences, Beijing, Beijing Municipality, China