

# Sapien 3 Transcatheter Aortic Valve Replacement in Young Aortic Valve Stenosis Patients From China

NCT06830499

---

Status	RECRUITING
Sponsor	Xijing Hospital
Enrollment	450 participants

## Key Eligibility Criteria

---

### Inclusion (7)

- years of age or older but  $\leq 70$  years old at time of consent.
  - Severe AS, defined as follows:
    - a) For symptomatic patients: i) Aortic valve area  $\leq 1.0$  cm<sup>2</sup> (or aortic valve area index of  $\leq 0.6$  cm<sup>2</sup>/m<sup>2</sup>), OR mean gradient  $\geq 40$  mm Hg, OR Maximal aortic valve velocity  $\geq 4.0$  m/sec by transthoracic echocardiography at rest b) For asymptomatic patients: i) Very severe AS with an aortic valve area of  $\leq 1.0$  cm<sup>2</sup> (or aortic valve area index of  $\leq 0.6$  cm<sup>2</sup>/m<sup>2</sup>), AND maximal aortic velocity  $\geq 5.0$  m/sec, or mean gradient  $\geq 60$  mm Hg by transthoracic echocardiography at rest, OR ii) Aortic valve area of  $\leq 1.0$  cm<sup>2</sup> (or aortic valve area index of  $\leq 0.6$  cm<sup>2</sup>/m<sup>2</sup>), AND a mean gradient  $\geq 40$  mm Hg or maximal aortic valve velocity  $\geq 4.0$  m/sec by transthoracic echocardiography at rest, AND an exercise tolerance test that demonstrates a limited exercise capacity, abnormal BP response, or arrhythmia OR iii) Aortic valve area of  $\leq 1.0$  cm<sup>2</sup> (or aortic valve area index of  $\leq 0.6$  cm<sup>2</sup>/m<sup>2</sup>), AND mean gradient  $\geq 40$  mmHg, or maximal aortic valve velocity  $\geq 4.0$  m/sec by transthoracic echocardiography at rest, AND a left ventricular ejection fraction  $< 50\%$ .
    - Tricuspid aortic valve stenosis and type-1 bicuspid aortic valve anatomy confirmed by MDCT.
  - The subject and the treating physician agree that the subject will return for all required post-procedure follow-up visits.
- ... and 2 more (see full listing online)

### Exclusion (18)

- Any of the following: a. no calcification; b. challenging calcification based on physician's experience and discretion (Case Review Board would decide whether to exclude challenging calcification cases).
  - Aortic valve is a congenital unicuspid valve, congenital Type-0 or Type-2 bicuspid valve, or quadricuspid valve.
  - Severe femoral, iliac or aortic atherosclerosis, calcification, coarctation, aneurysm or tortuosity, which prevents transfemoral TAVR.
  - Evidence of an acute myocardial infarction  $\leq 1$  month (30 days), with evidence of myocardial necrosis in a clinical setting consistent with acute myocardial ischemia.
  - Need for open heart surgery (including severe aortic regurgitation, mitral regurgitation or stenosis, or tricuspid regurgitation, congenital heart disease, AF, complex coronary artery disease).
- ... and 13 more (see full listing online)

## Locations (4 total)

---

Department of Cardiovascular Surgery of Xijing Hospital, Air Force Military Medical University, Xi'an, Shaanxi, China  
West China Hospital, Sichuan University, Chengdu, Sichuan, China  
Fuwai Hospital, Chinese Academy of Medical Sciences, Beijing, China  
... and 1 more locations

---

<https://clinicaltrials.gov/study/NCT06830499>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).