



Edwards SAPIEN 3 Transcatheter Heart Valve

Evaluating Transcatheter Aortic Valve Replacement (TAVR) in Asymptomatic Severe Aortic Stenosis Patients

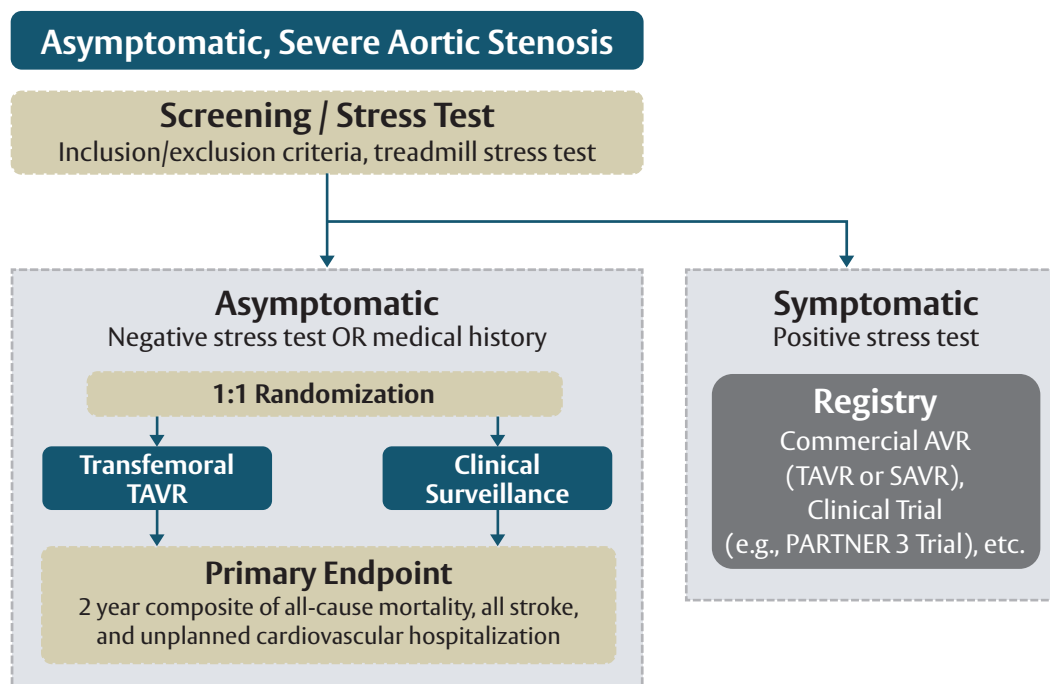
Trial Overview for Health Care Professionals

Background

- Most patients with asymptomatic severe aortic stenosis (AS) are followed clinically until symptomatic, left ventricular dysfunction develops, or cardiac surgery is recommended for other reasons.
- Practical challenges with clinical surveillance:
 - Interpreting symptoms may be difficult
 - AS progression is variable and rapid deterioration may go unnoticed by patients and physicians
 - Late symptom reporting may result in irreversible myocardial damage with worsened prognosis after AVR
- Whether early intervention before symptoms develop will improve outcomes remains unknown and has never been studied in a randomized trial.

Objective of the EARLY TAVR Trial

- Establish the safety and effectiveness of the Edwards SAPIEN 3 transcatheter heart valve compared with clinical surveillance in asymptomatic patients with severe AS.



Key Study Inclusion Criteria

- 65 years of age or older
- Severe aortic stenosis defined as:
 1. Aortic valve area (AVA) $\leq 1.0 \text{ cm}^2$ or AVA index $\leq 0.6 \text{ cm}^2/\text{m}^2$ AND
 2. Peak jet velocity $\geq 4.0 \text{ m/s}$ or mean gradient $\geq 40 \text{ mmHg}$
- Patient is asymptomatic defined as:
 1. Negative treadmill stress test, OR
 2. Physician assessment of patient history if unable to perform a stress test
- LV ejection fraction $\geq 50\%$
- Society of Thoracic Surgeons (STS) risk score ≤ 10

Patient Screening: Collaborative Process



For more detailed information about the EARLY TAVR Trial, visit www.clinicaltrials.gov



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¹ Genereux P. Natural history, diagnostic approaches and therapeutic strategies for patients with asymptomatic severe AS. JACC 2016; 2263-88

INVESTIGATIONAL DEVICES. CAUTION: The Edwards SAPIEN 3 transcatheter heart valve is an investigational device when used in asymptomatic patients. Limited by Federal (USA) law to investigational use only. These devices are not available for marketing or commercial sale in the United States for asymptomatic patients. See Instructions for Use for full information, including indications, contraindications, warnings, precautions, and adverse events.

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