

CORE VALVE CLINICAL TRIAL — CRITERIA (Page 1)

CoreValve is a Transcatheter Aortic Valve Implantation (TAVI) procedure, a minimally invasive treatment option for people with severe aortic stenosis. For more information, contact Fogarty Clinical Research Inc at 650-962-4512.

Inclusion Criteria

HIGH RISK SURGICAL ONLY

- Subject must have co-morbidities such that one cardiologist and two cardiac surgeons agree that predicted risk of operative mortality is $\geq 15\%$ (and predicted operative mortality or serious, irreversible morbidity risk of $< 50\%$) at 30 days.

EXTREME RISK ONLY

- Subject must have co-morbidities such that one cardiologist and two cardiac surgeons agree that medical factors preclude operation, based on a conclusion that the probability of death or serious morbidity exceeds the probability of meaningful improvement. Specifically, the predicted operative risk of death or serious, irreversible morbidity is $\geq 50\%$ at 30 days.
- Subject has senile degenerative aortic valve stenosis with mean gradient > 40 mmHg, jet velocity greater than 4.0 m/s, or an initial aortic valve area of ≤ 0.8 cm² (or aortic valve area index ≤ 0.5 cm²/m²) by resting echocardiogram.

Exclusion Criteria

CLINICAL

- Evidence of an acute myocardial infarction ≤ 30 days before the index procedure or randomization to OMM.
- Any percutaneous coronary or peripheral interventional procedure performed within 30 days prior to the index procedure or randomization for OMM with bare metal stents and 6 months with drug eluting stents (this part only for high risk surgical patients).
- Blood dyscrasias as defined: leukopenia (WBC < 1000 mm³), thrombocytopenia (platelet count $< 50,000$ cells/mm³), history of bleeding diathesis or coagulopathy, or hypercoagulable states.
- Untreated clinically significant coronary artery disease requiring revascularization.
- Cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support.
- Need for emergency surgery for any reason.
- Severe ventricular dysfunction with left ventricular ejection fraction (LVEF) $< 20\%$ as measured by resting echocardiogram.
- Recent (within 6 months) cerebrovascular accident (CVA) or transient ischemic attack (TIA).

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El Camino Hospital
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Exclusion Criteria (Continued)

- End stage renal disease requiring chronic dialysis or creatinine clearance < 20 cc/min.
- Active peptic ulcer or GI bleeding within the past 3 months.
- A known hypersensitivity or contraindication to any of the following which cannot be adequately pre-medicated:
 - » Aspirin
 - » Heparin (HIT/HITTS) and bivalirudin (only for Extreme Risk patients)
 - » Nitinol (titanium or nickel alloy)
 - » Ticlopidine and clopidogrel
 - » Contrast media
- Ongoing sepsis, including active endocarditis.
- Subject refuses a blood transfusion.
- Life expectancy < 12 months due to associated non-cardiac co-morbid conditions.
- Other medical, social, or psychological conditions that in the opinion of an Investigator precludes the subject from appropriate consent.
- Severe dementia (resulting in either inability to provide informed consent for the trial/procedure, prevents independent lifestyle outside of a chronic care facility, or will fundamentally complicate rehabilitation from the procedure or compliance with follow-up visits).
- Currently participating in an investigational drug or another device trial.
- Symptomatic carotid or vertebral artery disease.
 - » Additional Exclusion for High Risk Surgical only: Subject has been offered surgical aortic valve replacement but declined.
 - » Anatomical
- Native aortic annulus size < 20 mm or > 27 mm per the baseline diagnostic imaging
- Pre-existing prosthetic heart valve any position.
- Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation (3-4+)).
- Severe mitral (3-4+) or severe tricuspid regurgitation.
- Moderate to severe mitral stenosis.
- Hypertrophic obstructive cardiomyopathy.
- Echocardiographic evidence of intracardiac mass, thrombus or vegetation.
- Severe basal septal hypertrophy with an outflow gradient.
- Aortic root angulation $> 70^\circ$.
- Ascending aorta diameter > 43 mm unless the aortic annulus is 20-23 mm in which case the ascending aorta diameter > 40 mm.
- Congenital bicuspid or unicuspid valve verified by echocardiography.
 - » Vascular
- Transarterial access not able to accommodate an 18Fr sheath.