

CTSN Trial: Evaluations of Outcomes following Mitral Valve Repair/Replacement in Severe Chronic Ischemic Mitral Regurgitation

Objectives	To evaluate the safety and efficacy of mitral valve repair and mitral valve replacement for patients with severe ischemic mitral regurgitation (MR)
Study Design	Randomized multi-center trial
Target Population	Patients diagnosed with severe ischemic MR in need of surgical intervention
Rx arms	(a) mitral valve repair with annuloplasty and a sub-valvular procedure for severe tethering (b) mitral valve replacement and complete preservation of the sub-valvular apparatus
Sample Size	250 subjects; 90% power to detect an absolute difference of 15 ml/m ² in LVESVI (based on a 35% (replacement) v. 20% (repair) reduction in LVESVI)
Duration	24 months following randomization
1° Endpoints	Degree of left ventricular remodeling, as assessed by Left Ventricular End Systolic Volume Index (LVESVI) at 12 months
2° Endpoints	<ul style="list-style-type: none"> ○ All-cause mortality (<i>Principal secondary endpoint</i>) ○ Operative time, cardiopulmonary bypass (CPB) and cross clamp time ○ Blood loss and transfusion ○ MACE (death, stroke, worsening heart failure (+1 NYHA Class), CHF hospitalization, mitral valve re-intervention) ○ NYHA Classification and CCSC Angina class ○ Peak VO₂ (assessed by cardio-pulmonary stress test) ○ LOS for the index hospitalization and discharge location ○ Re-admission rates and days alive out of hospital ○ Echo parameters ○ Adequacy of revascularization ○ Change in quality of life (QOL) ○ Neurocognitive outcomes ○ Cost and cost effectiveness ○ Incidence of serious adverse events ○ Re-operation for MR and freedom from re-operation in general
Selected Inclusion Criteria	<ul style="list-style-type: none"> ○ Chronic severe ischemic mitral regurgitation by echocardiography using an integrative method ○ Eligible for surgical repair and replacement of mitral valve ○ Coronary artery disease with or without the need for coronary revascularization
Selected Exclusion Criteria	<ul style="list-style-type: none"> ○ Any evidence of structural mitral valve disease or ruptured papillary muscle ○ Prior mitral valve repair ○ Severe pulmonary hypertension ○ Contraindications to CPB ○ Inability to derive ERO and ESVI by transthoracic echocardiography ○ Planned concomitant intra-operative procedures (except closure of PFO, ASD or Maze procedure) ○ Clinical signs of cardiogenic shock at the time of randomization ○ Treatment with chronic intravenous inotropic therapy at the time of randomization ○ ST segment elevation MI requiring intervention within 7 days prior to randomization ○ Congenital heart disease (except PFO or ASD) ○ Chronic renal insufficiency defined by Cr ≥ 2.5 or chronic renal replacement Rx ○ Evidence of cirrhosis or hepatic synthetic failure