

CTSN Trial: Surgical Interventions for Moderate Ischemic Mitral Regurgitation

Objectives	To evaluate the safety and efficacy of mitral valve repair for moderate ischemic mitral regurgitation
Study Design	Randomized multi-center trial
Target Population	Patients diagnosed with moderate ischemic MR with a clinical indication for CABG
Rx arms	(a) Coronary Artery Bypass Grafting (CABG) + Mitral Valve Repair (b) CABG Alone
Sample Size	300 subjects; 90% power to detect an absolute difference of 12 ml/m ² in LVESVI (based on a 20% (repair) v. 5% (CABG alone) 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"> ○ MACE (death, stroke, worsening heart failure (+1 NYHA Class), CHF hospitalization, mitral valve [MV] re-intervention); (<i>Principal secondary endpoint</i>) ○ All-cause mortality ○ NYHA Classification and CCSC Angina class ○ Peak VO₂ (assessed by cardio-pulmonary stress test) ○ LOS for the index hospitalization and discharge location ○ Readmission rates & days alive out of hospital ○ Echo parameters <ul style="list-style-type: none"> ○ 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"> ○ Moderate mitral regurgitation by echocardiography, using an integrative method ○ Coronary artery disease amenable to coronary artery bypass grafting and a clinical indication for revascularization
Selected Exclusion Criteria	<ul style="list-style-type: none"> ○ Any evidence of structural (chordal or leaflet) mitral valve disease ○ Inability to derive ERO and ESVI by transthoracic echocardiography ○ Planned concomitant intra-operative procedures (except closure of PFO, ASD, or Maze procedure) ○ Prior surgical or percutaneous mitral valve intervention ○ Contraindication to cardiopulmonary bypass (CPB) ○ Clinical signs of cardiogenic shock at the time of randomization ○ Treatment with chronic intravenous inotropic therapy at the time of randomization ○ Severe, irreversible pulmonary hypertension in the judgment of the investigator ○ 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