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Percutaneous edge-to-edge repair for tricuspid regurgitation: study design and initial results from the TRILUMINATE clinical trial

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS
The TRILUMINATE trial has been initiated to determine the effectiveness of a recently developed tricuspid valve repair system. This system is designed to treat tricuspid regurgitation through percutaneous edge-to-edge repair. Herein we describe the design and initial observations from the TRILUMINATE clinical trial.

METHODS AND RESULTS
TRILUMINATE is a prospective, single arm, multi-center, international trial designed to evaluate the safety and effectiveness of an edge-to-edge tricuspid valve repair system in subjects with moderate or greater tricuspid regurgitation. The trial is powered to enroll a minimum of 85 subjects at 21 centers and has been approved for enrollment in 7 countries (Germany, United States, Spain, Italy, Switzerland, France, and Netherlands). Key subject inclusion criteria include: a) Presence of moderate or greater tricuspid regurgitation severity, b) Persistent symptoms (New York Heart Association Functional Class II or greater) despite being optimized on medical therapy, and c) High-risk for tricuspid valve surgery. An independent eligibility committee comprised of interventional cardiologists, cardiovascular surgeons, heart failure cardiologists, and echocardiographers confirms each potential subject for inclusion or exclusion into the trial. The primary effectiveness endpoint is reduction in tricuspid regurgitation of ? 1 grade at 30 days compared to baseline, and the primary safety endpoint is incidence of major adverse events at 6 months. Detailed echocardiographic evaluation of tricuspid valve/tricuspid regurgitation characteristics and right heart function are performed by an independent echocardiography core lab. The trial is currently underway, with the first 12 subjects enrolled as of March 2018.

CONCLUSIONS
The TRILUMINATE clinical trial is the first prospective, multicenter, international clinical trial designed to evaluate the edge-to-edge Tricuspid Valve Repair System for treatment of tricuspid regurgitation. Detailed study design and initial data from consecutive subjects enrolled into the trial, with core-lab adjudicated data, will be presented.

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