CHI St. Luke's Health

Baylor St. Luke's Medical Center

in partnership with

Texas Heart® Institute

Cardiology Research Newsletter

Office of Clinical Research

Spring 2015 • Issue Three

Heart Valve Clinical Research

TAVR

Portico*
St. Jude INC.
Joseph Coselli, MD

The PORTICO clinical trial is a prospective, multi-center, randomized, controlled clinical study, designed to evaluate the safety and effectiveness of the SJM Portico Transcatheter Heart Valve and Delivery Systems (Portico) via the transfemoral and alternative delivery method in patients that have been diagnosed with severe aortic stenosis.

With a composite endpoint of all cause mortality or disabling stroke at one year, the PORTICO trial will include a maximum of 1610 subjects (930 subjects in the high risk cohort and 680 subjects in the extreme risk cohort.

To obtain inclusion and exclusion criteria for valve studies, contact the Research Coordinator at 832.355.9301.

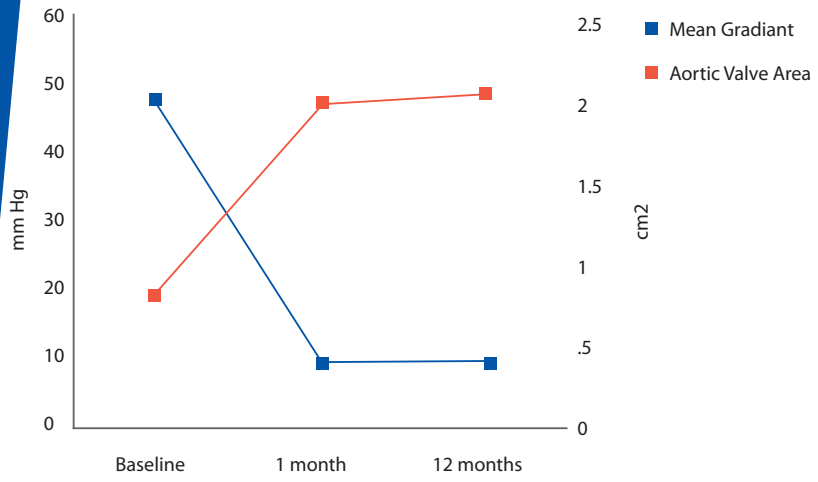
*Opening second quarter 2015

CoreValve
Medtronic
Joseph Coselli, MD

The CoreValve clinical trial is set to demonstrate the safety and effectiveness of the Medtronic CoreValve System for patients with severe symptomatic aortic stenosis who are high or extreme risk for surgical aortic valve replacement, as measured by composite of all cause death or major stroke at 12 months. The CoreValve Pivotal and Continued Access studies are no longer enrolling patients due to FDA approval in 2014. The CoreValve Expanded Use study is still in the process of enrolling patients that are diagnosed with severe aortic stenosis, NYHA III or greater, with a mean gradient >40mm HG and/ or peak velocity >4.0m/s and AVA ≤0.8cm$_2$ (to be determined by echocardiogram or heart cath). Further inclusion criteria for the CoreValve Expanded Use study are as followed:

- Severe mitral and/or tricuspid regurgitation
- End stage renal disease
- Low gradient low output
- TAV in SAV- for patients that have had a failed surgical aortic valve replacement

Core Valve High and Extreme Risk



Stem Cell Center Clinical Trials

PACE
Cardiovascular Cell Therapy Research Network (CCTRN):
Emerson C. Perin, MD

A randomized, double-blind, placebo-controlled trial that will assess the potential physiologic effect, clinical efficacy, and safety of autologous bone marrow derived aldehyde dehydrogenase bright cells delivered by intramuscular injections to patients with PAD and symptom-limited intermittent claudication.

DREAM-HF
TEVA Branded Pharmaceutical Products R&D, Inc:
Emerson C. Perin, MD

A double-blind, randomized, sham-procedure-controlled, parallel-group efficacy and safety study of allogeneic bone marrow derived MPCs in patients with chronic heart failure due to left ventricular dysfunction of either ischemic or non-ischemic etiology.

PARACHUTE IV
CardioKinetix Inc:
Emerson C. Perin, MD

The purpose is to evaluate the safety and effectiveness of the catheter based implantation of the CKI Parachute in the treatment of patients with NYHA Class III or IV (AMBULATORY) heart failure due to ischemic heart disease. The Parachute Implant isolates the dysfunctional region of the ventricle and decreases functional chamber volume.

For more information on stem cell clinical research, contact the Research Coordinator at 832-355-9405.