Sorin Group initiates PERSIST-AVR trial to evaluate Perceval sutureless aortic valve against standard sutured bioprostheses

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Sorin Group, a global medical device company and a leader in the treatment of cardiovascular diseases, today announced the initiation of ***PERSIST-AVR*** (**Per**ceval **S**utureless **I**mplant Vs **St**andard **A**ortic **V**alve**R**eplacement), the first international, prospective, post-market randomized multi-center trial evaluating the Perceval sutureless aortic valve compared to standard sutured bioprostheses in patients with aortic valve disease.

Engineered to restore and preserve natural valve performance, Perceval is a sutureless heart valve for patients who require an aortic valve replacement. As a new generation of aortic bioprostheses, the sutureless Perceval valve offers potential patient advantages including reduced ICU stay, ventilation time, and need for blood transfusion compared to traditional sutured valves.

“To date, the Perceval valve has demonstrated very promising performances, freedom from structural valve deterioration, improved patient postoperative outcome results and significant cost savings driven by reduced hospital stays and lower procedural expenses”, said Prof. Theodor Fischlein, M.D., Ph.D., Paracelsus Medical University Cardiovascular Center, Nuremberg, Germany, and Principal Investigator of the trial.

“PERSIST-*AVR* is the first large international multicenter trial on surgical aortic valve replacement since thirty years. This trial will provide a unique opportunity to further understand the valve’s safety and efficacy and potentially establish Perceval as the new gold standard in the surgical treatment of aortic valve disease,” said Dr. Roberto Lorusso, M.D., Ph.D., Maastricht University Medical Center, Maastricht, The Netherlands and Principal Co-Investigator of the trial.

The PERSIST-*AVR* trial will be conducted at 60 sites worldwide where Perceval obtained regulatory clearance. It is expected to recruit patients with severe symptomatic aortic stenosis or steno-insufficiency who are candidates for surgical replacement of their native aortic valve. The primary endpoint of the trial is to demonstrate non-inferiority of Major Adverse Cardiac Cerebrovascular Events (MACCE) at one year according to VARC-2 criteria. A Steering Committee was established and comprised of A.P. Kappetein (Rotterdam, Netherlands), M. Shrestha (Hannover, Germany), B. Meuris (Leuven, Belgium), T. Folliguet (Nancy, France), and E. Roselli (Cleveland, OH, USA).

The study is expected to enroll 1,234 patients within a two-year enrollment period and patients will be followed until five years post procedure.

“We are pleased to announce the initiation of the international PERSIST-*AVR* trial, the first trial of its kind,” said Michel Darnaud, President of the Cardiac Surgery Business Unit, Sorin Group. “While prior clinical trials on Perceval have demonstrated a reduction in patient hospital stays and improved patient outcomes, PERSIST-AVR is expected to give further evidence of Perceval compared to standard sutured stented bioprosthetic aortic valves.”

Source:
http://www.sorin.com/