Claret Medical completes enrollment of CLEAN-TAVI

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Claret Medical (Santa Rosa, California), a developer of solutions for cerebral protection during structural heart, vascular and cardiac surgery procedures, has completed enrollment in the CLEAN-TAVI clinical trial studying its filter-based cerebral protection system (CPS). The trial was designed to demonstrate the importance of cerebral protection in reducing the number and volume of new cerebral lesions created by debris lodged in the brain as a result of transcatheter aortic valve implantation (TAVI).

"The primary motivation for this study was to conduct the first side-by-side randomized study of this type of technology," Azin Parhizgar, president/CEO of Claret, told *Medical Device Daily*. "Before this study, that data didn't exist. There was anecdotal data or registry data or basically post hoc analyzed data from literature, but this is the first randomized one-to-one blinded study with a more than adequate patient sample size."

CLEAN-TAVI is a prospective, single blind, randomized, controlled trial of 100 patients treated with the **Medtronic** (Minneapolis) CoreValve, where the Claret Medical filter-based system was used for cerebral protection. The trial was conducted at the **University of Leipzig** (Lepzing, Germany), with Professor Axel Linke as the lead investigator.

The efficacy outcomes reported will be the resulting differences in the volume and number of embolic lesions detected in the brain pre- and post-TAVI procedure, with or without the use of cerebral protection, through a serial review of magnetic resonance imaging (MRI) performed over time. The MRI scans will be assessed blindly by an independent core lab overseen by Robert Zivadinov, of the **Buffalo Neuroimaging Analysis Center** (Buffalo, New York). Evaluation of patients' neurological and neurocognitive functions will also be performed, as well as blinded histopathological review of the captured debris by Renu Virmani at **CVPath Institute of Pathology** (Gaithersburg, Maryland). The trial will evaluate outcomes at two, seven and 30 days post-procedure, and at one year.

"CLEAN-TAVI is a landmark clinical trial, and we expect it to be the first to show a reduction in brain lesions associated with TAVI when cerebral protection is used," Linke said in a release. "As TAVI patients get younger and healthier, it will be unacceptable for the stroke rate to remain where it is today or for us to ignore the resulting neurocognitive decline associated with these lesions in the brain. This study may have significant implications for the expansion of TAVI into new patient populations in the years to come."

Data from the trial could appear as early as the Transcatheter Cardiovascular Therapeutics (TCT) annual meeting, which is scheduled from Sept. 13, to Sept. 17. The company would not go into specific detail about the data.

"The results are still under embargo, and the [results] are still being analyzed by the principle investigator in the core lab, but the results seem to be trending positive, and that's all I can say at this point," Parhizgar said.

Claret said that the device is the only filter-based device on the market that both captures and removes embolic debris released during TAVI procedures that could otherwise be a source of acute stroke. The system has been safely used in more than 800 procedures worldwide to date.

The company is currently vying for approval for the device in the U.S.

"The device is not yet approved for the U.S. market, yet but we have a pivotal study IDE that was approved for last quarter for conducting a full pivotal study in the U.S. Hopefully the plan is to do the first patient enrollment by TCT. This is a 285-patient study and it's slated for market entry into the U.S. by sometime in 4Q15."

In addition, the company said that it has initiated the SENTINEL-H post-market observational study evaluating its latest generation cerebral protection system, the Sentinel CPS. SENTINEL-H is a pan- European, core-lab adjudicated study enrolling up to 250 patients at 10 to 15 centers. The study is designed to evaluate the effectiveness of the Sentinel CPS in capturing debris during TAVI procedures. The primary endpoint of the study is the rate of capture and histomorphometric analysis of the embolic debris, including total and per-filter embolic debris volume lodged in the right and left carotid arteries, as well as characterization of the embolic material. The first patient was treated by Peter Frambach, in the **Centre Hospitalier de Luxembourg**. Associate Professor Christoph Naber, from **Elisabeth-Krankenhaus** (Essen Germany), is the principal investigator for the SENTINEL-H study. //

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