Medtronic News

First Patients Enrolled in Medtronic Clinical Study Designed to Identify Patients at High Risk for Sudden Cardiac Arrest in Developing Countries

Study Will Assess Defibrillator Therapy in Patients Most At-Risk for SCA

Minneapolis - March 27, 2014 -Medtronic, Inc. (NYSE:MDT) today announced the first patients were enrolled in the Improve SCA Clinical Study, a first-of-its-kind study that will identify patients in developing countries at a high risk for sudden cardiac arrest (SCA) - an abrupt loss of heart function that can lead to death in minutes - who have not previously experienced a life threatening arrhythmia (primary prevention patients). The first patients were enrolled at West China Hospital and Fuwai Hospital in China.

Patients enrolled in the study may be indicated for either an ICD, which administers electrical shocks or painless pacing therapy to stop the heart from quivering chaotically, or a CRT-D, which resynchronizes the contractions of the ventricles by sending tiny electrical impulses to the heart. Both devices are designed to stop a life-threatening fast or irregular heart rhythm that causes SCA, and are under-utilized in developing countries with typically less than 10 percent of indicated patients implanted.

"Defibrillation is the only definitive treatment for SCA, and while recent studies have proven ICDs are effective in reducing mortality for primary prevention patients in North America and Europe, our challenge has always been identifying those patients most at risk for SCA around the world," said Shu Zhang, M.D., of Fuwai Hospital in Beijing, China. "Improve SCA is the first study to evaluate the benefits of the therapy for high-risk patients in countries where defibrillation therapy for primary prevention of SCA is vastly underutilized."

It is estimated that 92 percent of people who suffer from sudden cardiac arrest will die within minutes without defibrillation. ICDs are 98 percent effective in stopping dangerous heart rhythms that can lead to Sudden Cardiac Death. [1], [2]

"The study will provide the clinical evidence needed to help primary prevention patients at the highest risk of SCA access the therapy they need, and has the potential to eventually influence local guidelines," said Dejia Huang, M.D., of West China Hospital in Chengdu City, Sichuan Province, China.

The Improve SCA study will build local clinical evidence to identify already indicated ICD/CRT-D primary prevention patients with additional risk factors that put them at a highest risk for SCA, such as:

- fainting (syncope),
- rapid transient abnormal heartbeats starting in the bottom chambers of the heart (non-sustained ventricular tachycardia or frequent premature ventricular contractions),
- or, decreased function of the heart (low ejection fraction).

The Improve SCA Clinical Study is expected to enroll approximately 4,800 participants that will be followed for two years. Approximately 100 sites will participate in more than 15 countries across Central and Eastern Europe (CEE), Asia, Middle East and Africa (MEA), India, and Latin America. The study is a prospective, non-randomized, multicenter study that will assess patients meeting current Class I guidelines for ICD (or CRT-D) device implant as defined by the American College of Cardiology, American Heart Association, Heart Rhythm Society (ACC/AHA/HRS) or European Society of Cardiology (ESC).

The study will test whether patients with a primary prevention indication for an ICD and one or more of these additional risk factors have the same risk of a having life threatening ventricular arrhythmia as those patients who have survived a prior episode of life threatening ventricular arrhythmia and are indicated for an ICD for secondary prevention of SCA.

"We are dedicated to improving the lives of patients most at risk for SCA and ensuring this patient population - which may benefit the most from defibrillation therapy - can get it," said Marshall Stanton, M.D., vice president and general manager of the

tachycardia business at Medtronic. "While leveraging our global expertise, we work to identify challenges at the local level and become part of a long-term solution. Improve SCA is our latest study that aims to help even more patients access the most innovative, life-saving therapies available today."

Results from the study may help clinicians identify and refer primary prevention patients for ICD/CRT-D therapy, and help more patients make informed decisions about receiving a defibrillator.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[1] Zipes, DP, Roberts, D. for the Pacemaker-Cardioverter-Defibrillator investigators. Results of the International Study of the Implantable Pacemaker Cardioverter-Defibrillator: A Comparison of Epicardial and Endocardial Lead Systems. Circulation. 1995;92:59-65.

[2] Volosin et. al. "Virtual ICD: A Model to Evaluate Shock Reduction Strategies." Heart Rhythm. Vol. 7, N. 5, May supplement 2010. (PO3-125).

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