

Medtronic Begins Study Evaluating Potential For Biventricular Pacing To Inhibit Heart Failure Progression

BLOCK HF clinical trial compares biventricular pacing with right ventricular pacing in people with early to mid-stage heart failure

MINNEAPOLIS, Jan. 22, 2004 - Continuing its leadership in research of device-based therapies to help the millions afflicted with heart failure, Medtronic, Inc., has initiated a major new clinical study designed to determine if biventricular pacing can slow the perilous progression of heart failure in people with mild to moderate heart failure symptoms (NYHA class I, II and III) and the need for a pacemaker. The study, called BLOCK HF, will compare the use of biventricular pacing delivered to both lower chambers of the heart with traditional pacing delivered to the lower right chamber of the heart.

Andrew Merliss, M.D., director of cardiac electrophysiology at the BryanLGH Heart Institute in Lincoln, Neb., was the first physician worldwide to implant a biventricular pacemaker for this important study. It is anticipated that up to 65 investigative institutions in the United States and Canada will participate in the implantation of the Medtronic InSync® III cardiac resynchronization device in up to 1,200 heart failure patients during the course of the study. The research is being conducted under an Investigational Device Exemption from the U.S. Food and Drug Administration.

"Heart failure, which is not uncommon in patients who require pacemakers to treat a slowly beating heart, is a progressive condition that weakens the heart's ability to pump effectively," said Dr. Merliss. "We are hopeful that earlier intervention with these new therapies may help to slow or reverse the debilitating effects of congestive heart failure in this population of patients. This trial should help us understand whether biventricular pacing will prove superior to standard pacing methods and whether it can play an effective role in helping these people fight the progression of heart failure during its earlier stages."

The study's principal investigator is Anne Curtis, M.D., professor of medicine and director of clinical electrophysiology at the University of Florida in Gainesville, Fla. "Resynchronization devices with biventricular pacing have rapidly been accepted by the cardiology community because of the immediate and dramatic improvement we have seen in many symptomatic heart failure patients," said Dr. Curtis. "However, research about cardiac resynchronization therapy so far has excluded patients with mild heart failure who need a pacemaker for traditional pacing indications. BLOCK HF is the first clinical study to assess whether biventricular pacing can slow the progression of heart failure in people with early heart failure symptoms who also need a pacemaker. If positive, this study could point to an unprecedented ability of a therapy to delay the progression of heart failure, one of the world's leading killers and causes for costly hospitalization."

Patients in the BLOCK HF trial will have mild to moderate heart failure accompanied by evidence of damage to cells that carry electrical signals from the upper to lower chambers of the heart, blocking the signal on one side of the heart (known as atrioventricular block or AV block). Because the heart's pumping function is weakened and the heart rate is compromised, the ventricles no longer pump sufficiently to meet the body's demand for life-sustaining oxygen. Approximately half of all Americans who have pacemakers have AV block, and of these 700,000 pacemaker patients with AV block, up to 25 percent of them may have heart failure.

All patients in the BLOCK HF study will receive an InSync III system initially programmed to traditional right ventricular pacing. They will then be randomized to either continue that therapy or have the device reset to pace both ventricles of the heart. The potential benefits of the therapy will be assessed using a composite endpoint that measures heart failure progression.

"We've entered a new era in the treatment of heart failure using device-based therapies, and the potential for extending life for millions of additional people while decreasing hospital costs with biventricular pacing is enormous," said Steve Mahle, president of Medtronic Cardiac Rhythm Management. "As the global leader in device-based heart failure therapies, one of Medtronic's highest business priorities is to partner with leading medical centers to research additional benefits of this already proven therapy for more patients. Since 1997, we have supported 20 heart failure clinical studies, including MIRACLE, MIRACLE ICD, SCD-HeFT and CARE-HF. The BLOCK HF study is just one of many new trials to come that will help discover new ways of treating people with heart failure."

Currently, biventricular pacing systems are approved in the United States and Canada for commercial use in people who have moderate to severe heart failure (NYHA class III and IV) and who have evidence of ventricular dysynchrony.

Heart failure is the most costly cardiovascular disease in the United States. The total cost of caring for U.S. heart failure patients is estimated to be up to \$40 billion per year.

Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, providing lifelong solutions for people with chronic disease. Its Internet address is <http://www.medtronic.com>.