Israel Ministry of Health Approves Clinical Trials for BioControl Medical's CardioFit® System in Heart Failure

The Associated Press

BioControl Medical [1], a medical device company headquartered in Yehud, Israel, has received approval from the Israel Ministry of Health to conduct a clinical trial of its CardioFit [2] ® system in patients with chronic heart failure [3] (HF) as part of INOVATE-HF. With the approval, Israel will join European countries and the United States to participate in the company's third phase of INOVATE-HF [4] (INcrease Of VAgal TonE in Heart Failure), a U.S. Food and Drug Administration-approved investigational device exemption (IDE) study of CardioFit being conducted in 80 centers worldwide.

Initiated in April 2011, INOVATE-HF is a prospective, randomized, controlled clinical study to determine the safety and efficacy of the CardioFit, an implantable electrical stimulation device designed to improve heart function and the first medical device to treat chronic heart failure using neurostimulation. The study will evaluate the system's potential to reduce hospitalization and death among patients with HF, while also exploring whether combined treatment with CardioFit and prescription drug therapy is more effective than drug therapy alone. 1 "This will be the first time we recruit patients in our own country for a clinical trial with the CardioFit," said Ehud Cohen, Ph.D., chief executive officer of BioControl Medical. "We have anticipated the day when we could bring our technology to patients in Israel, and it is only fitting that we are able to include our neighbors, family and friends in our ground-breaking INOVATE-HF trial." Three medical centers will participate in the study: Barzilai in Ashqelon; Bnai-Zion (Rothschild) in Haifa; and Kaplan in Rehovot. Patients diagnosed with Class III heart failure caused by left ventricular dysfunction who routinely take prescription drug therapy may qualify to participate in the trial. Patient recruitment is already underway.

"INOVATE-HF is an incredibly important trial that could offer new hope to patients with heart failure and provide medical professionals with new insights into how to treat and prevent the progression of the disease," said Prof. Uri Rosenschein, director of the department of cardiology, Bnai-Zion Medical Center and a lead investigator in the trial. "We are honored to be part of a potentially groundbreaking clinical trial for a product that was designed and developed in Israel." INOVATE-HF is designed to explore CardioFit's potential to help treat one of the hallmarks of HF: an imbalance in the autonomic nervous system, which regulates involuntary bodily functions including heart muscle activity. In healthy individuals, the two branches of the autonomic nervous system, called the sympathetic and the parasympathetic, work in concert to regulate the heart. At the most basic level, the sympathetic increases cardiovascular activity, while the parasympathetic decreases it. In people with HF, the balance between these two branches is disrupted, leading to added stress on the heart and progressive deterioration of cardiovascular function.

While prescription medications have been successful at treating the sympathetic branch to reduce select symptoms, there have been no treatments designed to specifically and safely target the parasympathetic branch. CardioFit was developed to activate the parasympathetic nervous system directly to reduce stress on the heart, thereby alleviating HF symptoms and reversing HF deterioration. It operates by stimulating the vagus nerve on the right side of the neck.

HF is a serious condition in which the heart cannot supply adequate blood flow and oxygen to the body. An estimated 100,000 people in Israel and 23 million people worldwide suffer from the disease, which is the leading cause of hospitalization in people over the age of 65.

References

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Links:

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