CHI St. Luke's Health

Baylor St. Luke's Medical Center

in partnership with

Texas Heart® Institute

Cardiology Research Newsletter

Office of Clinical Research

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Medtronic Micra™ Transcatheter Pacing System (TPS):

World's Smallest, Minimally Invasive Cardiac Pacemaker

Unlike traditional pacemakers, the Micra transcatheter pacemaker is a fully self-contained, miniaturized pacemaker designed to provide the most advanced pacing technology via a minimally invasive approach for patients with bradycardia.

The efficacy and safety of the Micra transcatheter pacemaker is currently being evaluated in a global clinical trial that will enroll up to 780 patients at approximately 50 centers including Texas Heart® Institute at Baylor St. Luke's Medical Center.

One-tenth the size of a conventional pacemaker, and comparable in size to a multi-vitamin, the Micra TPS pacemaker is delivered directly into the heart through a catheter inserted in the femoral vein. Once positioned, the pacemaker is securely attached to the heart wall and can be re-positioned or retrieved if needed. The miniature device does not require the use of leads to connect to the heart. Attached to the heart via small tines, the pacemaker delivers electrical impulses that pace the heart through an electrode at the end of the device.

John Seger, MD, the Principal Investigator for Micra at THI, in collaboration with Abdi Rasekh, MD, are recruiting patients with Class I or II indication for a single-chamber ventricular pacemaker. Micra is contraindicated in patients with current implanted cardiac devices that would interfere with Micra or are providing active cardiac therapy.

Why Micra?

Unmet Clinical Needs

- Access complications (pneumothorax, occlusion)
- Pocket complications (Hematoma, Erosion, infections)
- Lead complications (dislodgement, fracture, infections, connection errors, interaction with vasculature & heart structures, extraction complications)

Patient Preference

- Cosmetic appeal (lack of pocket)
- Minimally invasive approach
- Pain and discomfort associated with pocket

Efficiency

- Faster procedure?
- Possibility for lower complications?

Increase Access to Brady Therapy

- Availability of specialists in emerging markets

Lipid Rich Plaque Study

The Office of Clinical Research at Baylor St. Luke's has enrolled nine patients, to date, in the large-scale, multi-center, international study aimed at linking the presence of Lipid Rich Plaque (LRP) to the occurrence of major cardiac adverse events.

The LRP Study will determine the relationship in patients undergoing IVUS-NIRS (near-infrared spectroscopy) imaging between lipid-rich plaque detected by intracoronary NIRS at non-stenotic sites and subsequent coronary events from new culprit lesions at both the patient level (vulnerable patients) and the segment level (vulnerable plaques).

The study will be performed in patients undergoing IVUS-NIRS imaging (the index procedure) in whom a TVC catheter used for routine clinical indications. The study also will test the ability of multi-vessel NIRS scanning for LRP in coronary segments without significant stenoses as a means to predict new coronary events arising from a new culprit lesion (a non-index culprit lesion). Analyses will be performed at both the patient level (vulnerable patients) and the segment level (vulnerable plaques).

If and when it is determined that vulnerable patients and vulnerable plaques can be detected by multi-vessel NIRS scanning, the study will transition from a detection study to a treatment study.

More Information

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