ECG BELT FOR CRT RESPONSE STUDY

INTRODUCTION
Following CRT implant, approximately 20–25% of heart failure patients do not appear to improve. A key unmet need is a means to determine acute response to CRT pacing during implant and follow-up procedures. Such feedback may improve LV lead placement and programming, thus improving patient outcomes.

The primary purpose of this study is to evaluate the ECG Belt System as an additional diagnostic tool for optimizing CRT therapy by comparing left ventricular remodeling in ECG Belt managed CRT patients and a control CRT group.

BACKGROUND
The ECG Belt System employs multiple rows of electrodes applied to the anterior as well as posterior portions of the torso. The belt provides isochronal maps of electrical activation and metrics of electrical heterogeneity. These maps and metrics are computed during intrinsic rhythm as well as during pacing to determine the changes from intrinsic to pacing rhythm.

DESIGN
- Prospective, randomized 2:1:1 (ECG Belt, Control A, Control B), pre-market
- 400 randomized subjects
- 48 sites in US, Canada, and Europe

<table>
<thead>
<tr>
<th>Implant</th>
<th>ECG Belt arm (n=200)</th>
<th>Control arms (n=200)</th>
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</thead>
<tbody>
<tr>
<td>Post-implant</td>
<td>ECG Belt: Programming management</td>
<td>ECG Belt: Blinded data collection</td>
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<tr>
<td>6-9 months</td>
<td>Further ECG Belt research testing</td>
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PATIENT CRITERIA

Inclusion Criteria:
- Indicated for CRT, with QRS duration >110 ms, and planned to be implanted with a market-released Medtronic CRT device with AdaptivCRT and a Medtronic quadripolar lead
- Meets at least one of the following criteria
  - QRS duration < 150 ms
  - Prior documented Myocardial Infarction
  - Non-LBBB

Exclusion Criteria:
- Permanent/persistent AF or presenting with AF with ventricular rate ≥ 90 BPM
- Pre-existing or previous LV lead or other confounding devices e.g. Left Ventricular Assist Device, Vagal Nerve Stimulator
- Currently implanted with IPG or ICD with ≥ 10% RV pacing
- Complete AV block
- Enrolled in a concurrent study that may confound the results of this study
- Younger than 18 years of age

CONTACTS

Clinical Study Team:
- Mireille van Ginneken, Global Study Leader
- Katie Weiner, US Study Manager
- Jeff Gillberg, HF Research Director, Bakken Fellow

Sponsor:
- Medtronic, Inc.

Funding:
- Medtronic, Inc.

ClinicalTrials.gov:
- TBD

OBJECTIVES

Primary Objective:
- Demonstrate benefit of using the ECG Belt System on reducing LVESV from baseline to 6 months post-implant

Ancillary Objectives:
- Estimate the benefit of using the ECG Belt System on LVEF
- Estimate the benefit of using the ECG Belt System on change in quality of life
- Estimate the benefit of using the ECG Belt System on the Clinical Composite Score
- Characterize ECG Belt system related adverse events
- Assess the changes in LVESV from 6-9 months between subjects who have and have not used the ECG Belt at 6 months
- Assess the extent of ECG Belt guided programming changes across study visits

STATUS

Study Status: Site activation
Estimated Study Start Date: November 2016
Estimated Study Completion Date: September 2019