ECG Belt for CRT Response

Published: 05-06-2019
Last updated: 09-04-2024

The purpose is to compare ECG Belt Research System managed cardiac resynchronization therapy (CRT) patients and a control CRT group with respect to left ventricular (LV) remodeling..

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON48164

Source
ToetsingOnline

Brief title
ECG Belt

Condition

- Heart failures

Synonym
desynchronization, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: CRT device, CRT Response, ECG Belt, left ventricular end-systolic volume (LVESV)

Outcome measures

Primary outcome

Demonstrate benefit of using the ECG Belt Research System on reducing left ventricular end-systolic volume (LVESV) from baseline to 6 months post-implant compared to standard CRT.

Secondary outcome

To estimate the benefit of using the ECG Belt Research System on LVEF compared to standard CRT.

2. To estimate the benefit of using the ECG Belt Research System on change in quality of life compared to standard CRT.

3. To estimate the benefit of using the ECG Belt Research System on change in Six-Minute Walk Test distance compared to standard CRT.

4. To estimate the benefit of using the ECG Belt Research System on the Clinical Composite Score compared to standard CRT.

5. To characterize ECG Belt Research System-related AEs.

6. To assess the changes in LVESV from 6-9 months between subjects who have and have not used the ECG Belt Research System at 6 months.

7. To assess the extent of ECG Belt Research System guided programming changes across study visits.

Study description

Background summary

There are several unmet needs for patients with Heart Failure such as to reduce device complications, improve efficiency of care, and maximize CRT response.LV

lead position is an important factor governing CRT response. Based on physician surveys, a key unmet need for CRT implant procedures is a system/means to determine acute response to CRT pacing during the implant procedure. Such feedback may provide physicians the confidence that they are placing the LV lead in a location that will decrease cardiac electrical dyssynchrony while ensuring that all other clinical parameters are met including lead stability, avoidance of phrenic nerve stimulation and reasonable pacing capture thresholds. Such feedback may also be used during implant and/or follow-up to determine the most optimal pacing parameters in case of a multipolar LV lead. The ECG Belt Research System may provide a solution to this unmet need.

Study objective

The purpose is to compare ECG Belt Research System managed cardiac resynchronization therapy (CRT) patients and a control CRT group with respect to left ventricular (LV) remodeling.

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Study design

Prospective, interventional, randomized, multi-center, investigational, pre-market research study.

Upon screening of the baseline echo, eligible subjects will be randomized 2:1:1 to either the ECG Belt arm, control arm A, or control arm B respectively.

Intervention

Upon screening of the baseline echo, eligible subjects will be randomized 2:1:1 to either the ECG Belt arm, control arm A, or control arm B respectively. The latter two arms are identically treated up until the 6-month follow-up and will be called the control arm as a whole.
All subjects will undergo the ECG Belt Research System procedure per their randomization assignment. After the 9-month visit subjects will be exited

Study burden and risks

There may be allergenic reaction, skin redness or irritation or discomfort from the additional ECG Belt electrodes, minor pain or discomfort while attaching and detaching multiple electrodes to the skin, and discomfort due to lying on the ECG Belt.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Indicated for CRT, with QRS duration >=130 ms, and planned to be implanted with a market-released Medtronic CRT device and meets at least one of the following criteria:
o QRS duration < 150 ms
o Prior documented Myocardial Infarction
o Non-LBBB

Exclusion criteria

Permanent/persistent AF or presenting with AF

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	05-06-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	04-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03504020
CCMO	NL68823.100.19