PREcision Event Monitoring of PatienTs with Heart Failure

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The goal of the PREEMPT-HF study is to collect device and clinical event data to evaluate extended applications of the HeartLogicTM Heart Failure Diagnostic (HeartLogic) in a broad spectrum of heart failure (HF) patients with an implantable...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON48493

Source
ToetsingOnline

Brief title
PREEMPT-HF

Condition

- Heart failures

Synonym
cardiac arrest, congestive heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: Event monitoring, Extending HeartLogic applications, Heart Failure, Sensor data collection

Outcome measures

Primary outcome

Primary Objective

The primary objective of the PREEMPT-HF study is to investigate the

association between HF sensor data and 30-day HF readmissions.

Secondary outcome

Additional Objectives

1. Characterize HF sensor data for:

o Association with risk for device VT/VF therapy

o Phenomapping of HF events

o Association with non-HF hospitalizations including cardiac non-HF

events and non-cardiac events

2. Collect subject Sleep Incline Sensor data prior to and following reviewable

clinical events

3. Link study data to third-party data, such as Center for Medicare and

Medicaid Services (CMS) administrative claims (US only). Association of

clinical study events and sensor data with other data sources will be

investigated. Any study data linkage will abide by all applicable laws,

regulations, and data use agreements, and patients will be consented

accordingly.

Study description

Background summary

Heart failure (HF) is a complex clinical syndrome with high morbidity, mortality, and economic burden. Chronic HF is persistent, gradually progressive, and punctuated by episodes of acute worsening leading to hospitalizations. Therefore, there remains an unmet clinical need to slow the progression of HF and prevent hospitalizations.

Study objective

The goal of the PREEMPT-HF study is to collect device and clinical event data to evaluate extended applications of the HeartLogicTM Heart Failure Diagnostic (HeartLogic) in a broad spectrum of heart failure (HF) patients with an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D). There are no primary safety and/or efficacy endpoints for this study.

Study design

The PREEMPT-HF study is a global, multi-center, post-market prospective, non-randomized study.
1. Subject Consent and Enrollment Visit (post implant)
2. Baseline Visit: (Must occur >=7 days post implant and <= 30 days post enrollment)
3. Interim Medical Record Review: [NO subject visit required] 6 Month
4. Final Clinic Visit: 12 Month
5. Study exit

Study burden and risks

There are no required treatments or therapeutic interventions in this trial.
The study involves the collection of sensor data and clinical event data. There are no additional risks of participating above those associated with standard of care.
Please refer to the Directions for Use for an overview of anticipated adverse (device) effects, and risks associated to the commercial device(s).
There may be no benefits to a subject*s participation in the study. However, participation may help future patients benefit from enhanced performance of the HeartLogic algorithm.

Contacts

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Scientific
Boston Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Subject is age 18 or above, or of legal age to give informed consent specific to each
country and national laws
• Subject has a documented diagnosis of heart failure
• Subject has a Boston Scientific CRT-D or ICD device implant that has HeartLogic,
with Heart Failure Sensors turned ON, Respiratory Sensor turned ON, and Sleep Incline Sensor turned ON
• Subject has an active bipolar RV lead implant.
• Subject is enrolled in LATITUDE (NXT 5.0 or future version), and is willing to be
remotely monitored from the baseline visit for approximately 12 months with

HeartLogic disabled

Exclusion criteria

• Subject has received or is scheduled to receive a heart transplant or ventricular assist device (VAD).
• Subject is enrolled in any concurrent clinical study without prior Boston Scientific written approval (excluding registries).
• Subject has a life expectancy of less than 12 months.
• Subject has a history of non-compliance to medical care or known inability to comply with requirements of the clinical study protocol.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2019
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	26-08-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
CCMO	NL67313.058.19