Multisensor Chronic Evaluations in Ambulatory Heart Failure Patients (MultiSENSE)

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

Summary

ID

NL-OMON37715

Source
ToetsingOnline

Brief title
MultiSENSE

Condition

- Heart failures

Synonym
heart Fialure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ambulatory, Heart Failure, sensors, SRD-1

Outcome measures

Primary outcome

It is estimated that approximately 100 events will be required for developing a

multisensory algorithm for the early detection of HF events.

Secondary outcome

NVT

Study description

Background summary

Chronic heart failure (HF) has a worldwide rate of incidence and prevalence of almost epidemic proportions. In the United States, 5.7 million patients have HF with about 670,000 new patients diagnosed every year. It is estimated that over 50 million Medicare beneficiaries will have HF by 2020 2. Over 1 million annual hospitalizations result from HF, accounting for about 70% of the total HF-related economic burden estimated at $56 billion per year. In 51 countries represented by the European Society of Cardiology there are at least 15 million HF patients that account for about 2% of the expenditure on health, mostly due to the cost of hospital admissions. Patient monitoring and management aimed at preventing hospitalizations could not only benefit health care economics but also improve patient quality of life and avoid HF hospitalizations correlated to disease severity or progression.
The pathophysiological mechanisms that lead to acute decompensated HF and its associated hospitalizations are complex - however, the large majority of HF hospitalizations occur from symptoms related to volume overload. Traditional methods of physical examination have limited sensitivity and specificity, and require frequent patient visits. Sensors integral to Boston Scientific*s CRV devices and the remote monitoring LATITUDE infrastructure provide a unique platform to continuously monitor patients for sub-clinical changes in HF status and alert the clinician to an impending worsening HF event. The feasibility of monitoring HF status using implanted device sensors has been shown, and studies are ongoing to determine efficacy for preventing hospitalizations. The detection performance of some individual sensor algorithms are reported to range from 50% to 70% sensitivity with 1.5 to 2.5 false positives per

patient-year, while providing an advance warning of about 2 weeks. The primary goal of the MultiSENSE study is to determine if integrating information from judiciously selected HF sensors in Boston Scientific*s CRT-D devices can improve detection performance.

Study objective

The purpose of the MultiSENSE study is to collect chronic ambulatory data simultaneously from multiple sensors in CRT-D devices in order to develop algorithms for the early detection of worsening HF.
The primary objectives of this study are to determine how ambulatory sensor measurements change with worsening HF, and to develop multisensor detection algorithms.
Additional data will be collected to compare sensor measurements against reference measurements when the subject is hospitalized for HF. Data from this study may also be used for determining prospective endpoints and sample sizes for future studies.
There are no formal statistical primary or secondary endpoints defined for this study. Therefore, no formal tests of hypothesis will be conducted.

Study design

The MultiSENSE study is a multi-center, international, prospective, non-randomized, feasibility, significant risk IDE study.Subjects included in the study will be followed for up to 15 months. Subjects will have their devices converted to an SRD-1 no earlier than 30 days post-implant and no later than 44 days post-enrollment. After conversion, subjects will be followed for a maximum of 12 months. Following device re-conversion the subject will be followed for an additional 30 to 44 days.
Once the subject*s COGNIS device is converted to a SRD-1, sensor data will be continuously stored in device memory. Data stored in the SRD-1 will be recovered from the implanted device using either subject follow-up visits to the investigational center, or using remote LATITUDE downloads.
The duration of the MultiSENSE study is expected to be four (4) years.

Study burden and risks

The MultiSENSE study is a significant risk IDE study. Investigational software will be downloaded into an implanted COGNIS device to convert it to a Sensor Research Device (SRD-1). Following conversion, the SRD-1 PG will provide study data collection features while maintaining all essential therapy and diagnostic features of the COGNIS. At the completion of the subject*s participation in the study, the SRD-1 will be restored to a COGNIS device.
The main risk is that the subject should seek device related care (routine or emergency) at an investigating center and that the device longevity will be reduced by up to 6 months. The subject may receive a benefit from an increased

follow-up schedule. Participation in this study is intended to provide the necessary data to develop future algorithms for detection of worsening HF events.

Contacts

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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

Age 18 or above, or of legal age to give informed consent specific to state and national law;Willing and capable of returning for all follow-up visits and emergency care at the investigational center, as medically appropriate;Willing to participate in all testing associated with this clinical investigation at an approved clinical investigational center;Currently implanted with a CRT-D system including a COGNIS device (Model N119, N120, P107 or P108) with RA, RV, and LV leads;Classified as NYHA Class II, III, or IV within the last 6 months

Exclusion criteria

Inability or refusal to sign the Patient Informed Consent
Inability or refusal to comply with the follow-up schedule
Documented as pacemaker dependent
Unable to rest comfortably in a semi-recumbent position for up to 20 minutes
Implanted with active Medtronic Fidelis® lead models: 6930, 6931, 6948 or 6949
Currently implanted with unipolar RA, RV, or LV leads
LV sensitivity programmed to <0.7mV AGC
Subjects that have a history of appropriate Tachycardia Therapy (external or implanted) for rates <165 bpm within 1 week prior to enrollment
Device battery status indicates approximate time to explant <2 years
Likely to undergo lead or PG revision during the course of the study as determined by the Investigator

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	12-12-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NCT01128166
CCMO	NL39229.058.12