A Frequent Optimization Study Using the QuickOpt Method

Published: 11-09-2007
Last updated: 08-05-2024

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Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON30958

Source
ToetsingOnline

Brief title
FREEDOM trial

Condition

- Heart failures

Synonym
Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: firma St. Jude Medical,St. Jude Medical

Intervention

Keyword: Cardiac Resynchronization Therapy, Heart Failure

Outcome measures

Primary outcome

The primary objective of this clinical investigation is to demonstrate that the proportion of improved patients in the treatment group is superior to the proportion in the control group, 12 months post-implantation.

The Heart Failure Clinical Composite Response22 will be used to evaluate the status of the patient.

Secondary outcome

The secondary objectives of the study are:

* All-cause, cardiovascular and heart failure mortality;

* All-cause, cardiovascular and heart failure hospitalizations.

Study description

Background summary

Cardiac resynchronization therapy (CRT) through simultaneous biventricular (BiV) pacing has emerged as an effective treatment in patients with heart failure (HF). Various studies have demonstrated the clinical benefit of CRT from improvements in quality-of-life, heart failure symptoms, exercise capacity, mortality, and hospitalization rates1-5. These studies support the therapeutic value of ventricular resynchronization in patients with severe HF (NYHA class III-IV) who do not have a standard indication for the implantation of a pacemaker.
It has been well known that atrio-ventricular (AV/PV) delay in CRT is a critical parameter for hemodynamic performance. While the first generation CRT devices simultaneously stimulated both the right ventricle (RV) and left ventricle (LV), newer devices provide the capability of adjusting the inter-ventricular (VV) pacing delay as well as the sequence of RV versus LV stimulation. Recent clinical studies have also shown that optimization of the

VV delay during BiV pacing can incrementally improve cardiac function over simultaneous BiV pacing6-15. However, the optimization of AV/PV and VV delays currently relies on echocardiography and/or Tissue Doppler Imaging (TDI) techniques, which are expensive and time consuming procedures and require extended office visits.
St. Jude Medical has developed a novel intracardiac electrogram (IEGM) method to estimate both the optimal AV/PV and VV delays. The IEGM based VV delay optimization method aims to synchronize electrical activation of the conducted intrinsic and paced wavefronts between the pacing electrodes. The IEGM based AV/PV optimization method characterizes the inter-atrial conduction patterns in order to maximize preload and to allow for proper timing of mitral valve closure. Based on the positive results from preliminary studies16,17, this IEGM based optimization method was incorporated as an automatic, programmer-based algorithm (referred as QuickOptTM) for measuring IEGMs and recommending patient specific optimal AV/PV and VV delays. Recently, an Investigational Device Exemption (IDE) trial was conducted with 115 patients to determine if the QuickOptTM optimization method showed correlation with echo optimization of AV/PV and VV delays18. The results of this prospective, nonrandomized, multicenter trial demonstrated a strong concordance correlation of over 96% for the maximum aortic velocity time integral (AVTI) measured at optimal AV/PV and VV delays between the QuickOptTM method and the AVTI echocardiography optimization technique.
Recent studies have shown that AV/PV and VV delays change overtime and re-optimization of these delays might be beneficial for maintaining significant improvement of cardiac function19-21. However, the benefits of re-optimization in terms of improvements in symptomatic status, fewer hospital admissions and reduced mortality still need to be evaluated.

Study objective

The purpose of this study is to demonstrate that frequent AV/PV and VV delay optimization using QuickOpt* in patients with CRT-D device results in improved clinical response over standard of care (i.e. empiric programming or one-time optimization using any non-IEGM optimization methods).

Study design

This clinical trial is an international, multicenter, prospective, randomized, parallel, double-blind study designed to compare frequent AV/PV and VV delay optimization using the QuickOpt method to standard of care (i.e. empiric programming or one-time optimization using any non-IEGM optimization methods). All patients taking part in this study be enrolled within 2 weeks of implantation. At that time, the patients will berandomized in a 1:1 fashion to one of the two groups (See figure 1):
* Control group: standard of care (i.e. empiric programming or one-time optimization using any non-IEGM optimization methods);

* QuickOpt* group: Frequent AV/PV and VV delay optimization using QuickOpt*.

Patients are followed for 12 months, with protocol scheduled visits at 3, 6, 9 and 12 months post-implantation (± 2 weeks).

Study burden and risks

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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

- patient meets current CRT-D indications and be impanted with an SJM CRT-D device with V-

V timing and a compatible lead system
- patient had the ability to complete a 6-minute hall walk with the only limiting factor to be fatique of shortness of breath.
- patient older than 18 year.

Exclusion criteria

- patient is less than 18 years old.
- patient has persistent of permanent AF.
- patient has the ability to walk > 450 meters in 6 minutes.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	36
Type:	Anticipated

Medical products/devices used

Generic name:	Cardiac Resynchornization Defibrillator
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	11-09-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL17480.041.07