Optimal Programming to Improve Mechanical Indices, Symptoms and Exercise in Cardiac Resynchronization Therapy

Published: 28-04-2009
Last updated: 06-05-2024

To demonstrate that QuickOptTM facilitated optimization of AV and VV timing in the initial 9 months following successful CRT-D will increase the rate of clinical response and structural remodeling at 12 months compared to usual care.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON33558

Source
ToetsingOnline

Brief title
OPTIMISE CRT

Condition

- Heart failures

Synonym
Cardiomyopathy, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical

Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: AV and VV Timing, Cardiac Resynchronization Therapy, Optimal Programming AV and VV Time

Outcome measures

Primary outcome

A combination of symptomatic improvement (>= 1 class reduction in specific

activity scale or >= 25% improvement in 6 minute walk test distance) and LV

remodeling (>= 15% decrease of LV end systolic volume or >= 5% increase in LV

EF).

Secondary outcome

• Rate of late (12-month) response to CRT

• Changes in BNP in correlation to cardiac remodeling

• Inter- / intra-ventricular dyssynchrony compared to usual optimization

Study description

Background summary

Cardiac resynchronization therapy (CRT) is primarily designed to synchronize the mechanical activity of the heart. While CRT is beneficial in average, a sizable proportion of patients do not clearly benefit from (respond to) CRT. Whether routinely optimizing the timing between the atria and ventricles (AV timing) and the timing between the left and right ventricles (VV timing) will significantly increase the likelihood of patients benefiting from (responding to) CRT is unknown.

Study objective

To demonstrate that QuickOptTM facilitated optimization of AV and VV timing in the initial 9 months following successful CRT-D will increase the rate of clinical response and structural remodeling at 12 months compared to usual

care.

Study design

This post market study is a double-blind, randomized, prospective, multicenter, parallel design with a control group.

Intervention

Group 1 has optimalization of A-V and V-V delays using Quickopt at 3, 6, 9 and 12 months after implantation.
Group 2 has a one time only optimalization of the A-V and V-V delays according to the standard hospital protocol within 4 weeks after implantation.

Study burden and risks

The risks involved with this study are similar to those associated with implantation and follow-up of other commercially available CRT-D system. There should be no additional risks to the patients assigned to the study.

Drawing blood for BNP at baseline, 3 and 12 months will give a small risk on bruises.

The burden is mainly a time burden of around 6 hours for the whole study.

Contacts

Public
St. Jude Medical

Standaardruiter 13
3905 PT Veenendaal
Nederland
Scientific
St. Jude Medical

Standaardruiter 13
3905 PT Veenendaal
Nederland

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 implanted with an SJM CRT-D device with V-V timing and a compatible lead system.
• Patient has the ability to complete a 6-minute hall walk with the only limiting factor to be fatigue or shortness of breath.
• Patient is geographically stable and willing to comply with the required follow-up schedule.
• Adequate echocardiographic images to measure LV end systolic volume

Exclusion criteria

• Patient has an epicardial ventricular lead system.
• Patient has the ability to walk >= 450 meters in 6 minutes
• Patient has limited intrinsic atrial activity (<= 40 bpm).
• Patient has persistent or permanent AF.
• Patient has a 2° or 3° heart block.
• Patient*s life expectancy is less than 1 year
• Patient is less than 18 years old.
• Patient is pregnant.
• Patient is on IV inotropic agents.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-02-2009
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	28-04-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL25730.091.09