Adaptive CRT optimization at rest and during exercise

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AdOpt CRT is designed to compare indices of cardiac function at device settings optimized using an investigational Adaptive CRT (aCRT)algorithm versus CRT with nominal programming. The comparison will be performed during rest and submaximal exercise...

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

Summary

ID

NL-OMON37566

Source
ToetsingOnline

Brief title
AdOpt CRT

Condition

- Heart failures

Synonym
heartfailure, resynchronisation therapy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: aCRT software, CRT-D, exercise test, Optimalization CRT

Outcome measures

Primary outcome

Compare Stroke Volume (SV) between BiV pacing with aCRT settings and BiV with nominal programming. The comparison will be performed at rest and during submaximal exercise.

Secondary outcome

* Compare Blood Pressure-derived (Pulse Pressure and Stroke Volume) and ECHO-derived (Left-Ventricular Ejection Fraction, Left-Ventricular Pre-ejection Interval and Ejection Time) parameters of cardiac function between BiV pacing with aCRT settings and BiV with nominal settings. The comparison will be performed during resting rate and during submaximal exercise.

* Compare Blood Pressure-derived (Pulse Pressure and Stroke Volume) and ECHO-derived (Left-Ventricular Ejection Fraction, Left-Ventricular Pre-ejection Interval and Ejection Time) parameters of cardiac function between BiV pacing and intrinsic conduction at rest and during submaximal exercise.

* Investigate changes in electrical conduction during submaximal exercise.

Study description

Background summary

Protocol page 6-8.

Cardiac resynchronization therapy (CRT) results in symptomatic improvement, reverse left ventricular remodeling and greater survival in patients with NYHA class III/IV heart failure, low ejection fraction (<=35%) and prolonged QRS duration (>120 ms). However, approximately 30% of CRT recipients show no benefit with the therapy. Multiple studies have demonstrated that optimization of CRT device atrio-ventricular (AV) and inter-ventricular (VV) delays can further improve cardiac function acutely and result in better clinical outcomes. Although consensus on the best optimization method is lacking, echocardiographic optimization is most common in clinical practice. Yet, the majority of CRT patients are not optimized, since the echocardiographic procedure is time and resource-consuming and settings optimal during in-office evaluation at rest may not be optimal at later times when the patient is active or when chronic changes in cardiac structure and function take place.
The aCRT algorithm is designed to optimize the AV and VV delays easily, automatically and continuously.

Study objective

AdOpt CRT is designed to compare indices of cardiac function at device settings optimized using an investigational Adaptive CRT (aCRT)
algorithm versus CRT with nominal programming. The comparison will be performed during rest and submaximal exercise.

Study design

AdOpt CRT is a prospective, multi-center, non-randomized investigational study. The duration of the study is expected to be approximately 1 year from the date of the first enrollment. The study will be performed at up to 10 centers in Europe, and is expected to enroll up to 50 subjects to meet the study objectives.
Data are collected at baseline and during the exercise test. The test day must take place within 14 days after the baseline visit. This could also be on the same day. There is no futher follow-up of the patients.

Intervention

Patients undergo an exercise stress test with ultrasound measurements and continuous blood pressure measurement. They will also receive a Holter during the test. The test is performed at different settings of the CRT-D.

Study burden and risks

Potential risks associated with participating in the study are:
• The operation of the algorithm aCRT may inadvertently cause a rapid and irregular heart beat, which can feel uncomfortable.
• The aCRT algorithm may cause your CRT-D device does not provide therapy or stimulate your heart so that the symptoms of heart failure (such as shortness of breath, weakness) may be aggravated.
• It is possible that the aCRT algorithm does not work as planned and shuts off.
• The aCRT algorithm may cause your CRT-D device accidentally gives a shock.
• There can be confusion about the operation of your device when someone not familiar with the aCRTalgoritme, evaluates the device. This can lead to inappropriate programming of the device.

Submaximal exercise may be associated with various side effects, which include shortness of breath, fatigue, nausea, palpitations, chest pain and, in rare instances, may be associated with the risk of myocardial infarction.

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

* 18 or greater.
* sign and date study Informed Consent form.
* Subject implanted with a clinically indicated CRT-D device (Medtronic Vision 3D or Protecta models) for at least 1 month but less than 7 months

Exclusion criteria

* history of persistent or permanent AF
* atrial or ventricular tachyarrhythmias or frequent atrial or ventricular ectopy at the time of enrollment.
* resting heart rate at the time of enrollment exceeds 90 bpm.
* CRT system implanted for more than 7 months
* complete AV block.
* previous mechanical valve surgeries.
* congenital heart disease.
* contraindication for an exercise test.
* unable to perform a sub-maximal exercise test.
* It is not possible to acquire technically acceptable echocardiographic images.
* medical conditions that would limit study participation.
* Subject is enrolled in the Adaptive CRT study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start

Start date (anticipated):	01-01-2012
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Generic name:	aCRT donwload software
Registration:	No

Ethics review

Approved WMO Date:	09-02-2012
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NCT01475175
CCMO	NL38885.101.11