Optimization of Cardiac Resynchronization Therapy at rest and during exercise conditions.

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

Summary

ID

NL-OMON35451

Source
ToetsingOnline

Brief title
OPTI-CARE

Condition

- Heart failures

Synonym
heart failure, ventricular dyssynchrony

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Boston Scientific / Guidant St. Paul. 4100 Hamline AV. North, St. Paul, MN 55112- USA.,Guidant / Boston

Scientific Corporation;St Paul;MN;USA.

Intervention

Keyword: CRT, Dobutamine, Optimization

Outcome measures

Primary outcome

The difference, in milliseconds, between the optimal AVD/VVD during resting conditions versus exercise.

Secondary outcome

To reach the secondary objectives, the following parameters are also measured: the intrinsic atrio- and interventricular conduction times on the intracardiac electrogram; coronary sinus dP/dt; a matrix with the dP/dt for all possible combinations of AVD*s and VVD*s. Moreover echocardiographic indices of mechanical asynchrony during rest and dobutamine infusion are determined.

Study description

Background summary

The aim of cardiac resynchronization therapy (CRT) is to correct ventricular dyssynchrony with a biventricular pacemaker and thereby diminish systolic dysfunction in patients with chronic heart failure. Individualized optimization of the atrioventricular delay (AVD) and interventricular delay (VVD) by echocardiography or invasive pressure measurements (dP/dt) is a cardinal component for the benefits. The optimal AVD/VVD during resting conditions is programmed in the CRT device. This fixed AVD/VVD could diminish the positive effect of CRT on the systolic function during exercise or even be counterproductive. In healthy subjects, the AVD shortens with exercise, and in three small monocenter studies the optimal AVD either lengthened or shortened. Nothing is published about the optimal VVD during exercise. This study will determine the difference between the optimal AVD/VVD during rest and exercise and a shortening of both AVD and VVD is expected during exercise.

Study objective

The primary objective of the study is to determine whether the optimal atrioventricular delay and interventricular delay in cardiac resynchronization therapy are a function of exercise. Secondary objectives are the development of an automatic algorithm for VVD optimization; to determine whether the optimal AVD is a function of the VVD and vice versa; to compare the left ventricular rate of pressure rise (dP/dt) to the dP/dt in the coronary sinus; to determine whether the optimal AVD/VVD are correlated to the intrinsic atrio- and interventricular conduction times; to determine whether the changes in optimal AVD/VVD during rest and exercise are related to the changes in mechanical dyssynchrony during rest and exercise.

Study design

This is a prospective single center observational study with invasive measurements. During CRT implantation the optimal AVD and VVD are determined by left ventricular dP/dt measurements using the Flexstim II pacemaker-/computersystem. The measurements during resting conditions are compared to those during dobutamine infusion (a simulation of exercise).

Study burden and risks

The implanted pacemakerleads are temporarily connected to the external Flexstim II system. To prevent infection, a maximum implantation duration is effectuated. The use of the Flexstim II will lead to more accurate and precize determination of the optimal AVD and VVD and therefore better acute hemodynamics.
The optimization procedure during dobutamine infusion will add approximately 30 minutes to the implantation procedure. The echocardiogram during dobutamine infusion also takes approximately 30 minutes. Dobutamine is not an experimental drug and the safety of the infusion protocol is proven during the use in stress echocardiograms, stress MRI*s and myocardial perfusion imaging. Potential side effects are usually well tolerated and a slower infusion rate or cessation of infusion will in general revert these side effects.The study results will not be implemented in the study subjects but might in the future, after further research, have therapeutic benefit for the subjects.
To measure the dP/dt in the coronary sinus, a wire with pressure sensor is temporarily inserted in this vein. The results can potentially lead to an advantage for future CRT patients.
Transthoracic echocardiography is a safe and noninvasive procedure without adverse side effects.

Contacts

Public
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Indication for Cardiac Resynchronization Therapy according to the current international guidelines. (See research protocol: chapter 5.2)

Exclusion criteria

Criteria for the complete study: (see also research protocol chapter 5.3)
-Contraindications for implantation of a CRT device;
-Age <18 years or incapacitated adult;
-Participation in another clinical study that prohibits any procedures other than standard;
-Pregnancy;
-Severe aortic stenosis with a valve area <1,0 cm2 or aortic valve replacement in

history.;Specific criteria for the infusion of dobutamine (see research protocol chapter 5.3 and 6.2.1):
-Significant abnormalities on coronary angiogram or myocardial perfusion scan (part of standard procedure before CRT implantation) that are not treated by coronary artery bypass graft or percutaneous coronary intervention;
-Atrial fibrillation with a fast ventricular response (heart rate >100 bpm);
-Baseline heart rate <10 beats per minute below target heart rate;
-Sinus bradycardia <40 beats per minute at baseline;
-Open operation wound for more than 3 hours before start of dobutamine infusion (only applies to dobutamine infusion during device implantation);
-Contraindications for dobutamine (baseline systolic blood pressure >180 mmHg or <80 mmHg, hemodynamic significant left ventricular outflow tract obstruction, aortic aneurysm, aortic dissection);
-Insufficient image quality during echocardiography at rest (only applies to dobutamine stress echocardiography);
-Experienced secondary endpoint (side effect) during dobutamine stress echocardiography (only applies to dobutamine infusion during device implantation).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2008
Enrollment:	51
Type:	Actual

Medical products/devices used

Generic name:	external pacemaker- / computersystem FlexstimII (Guidant/Boston Scientific Corporation;CE label pres
Registration:	No

Ethics review

Approved WMO Date:	19-08-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-09-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-03-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-10-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-09-2010
Application type:	Amendment
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	NL22307.041.08