QRS vector analysis for optimizing timing of biventricular pacing in cardiac resynchronization therapy

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

Summary

ID

NL-OMON34250

Source ToetsingOnline

Brief title Vectorcardiography for CRT optimization

Condition

• Heart failures

Synonym heart failure and left bundle branch block

Research involving Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht **Source(s) of monetary or material Support:** Ministerie van OC&W

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Intervention

Keyword: Cardiac Resynchronization therapy, Heart failure, Left bundle branch block, Vectorcardiography

Outcome measures

Primary outcome

Main study endpoints are the relation between the QRS vector analyzed from

three-dimensional vectorcardiography, values of inter-ventricular asynchrony

and improvement in LV pump function in CRT patients.

Secondary outcome

Study description

Background summary

In patients with heart failure and left bundle branch block (LBBB), cardiac resynchronization therapy (CRT) improves cardiac pump function, clinical status, and survival by restoring the LBBB induced asynchronous ventricular contraction. However 30-50% of patients show little or no response to the therapy. Optimal application of CRT using biventricular (BiV) pacing requires appropriate programming of atrioventricular (AV)-delay and interventricular (VV)-interval on an individual basis. However, extensive individual optimization is often not practical or feasible in routine clinical practice. Preliminary results from animal studies revealed a linear relation between measurement of interventricular asynchrony and the QRS vector derived from the surface ECG in BiV pacing. Moreover, the optimal improvement in left ventricular (LV) pump function during BiV pacing was shown to be halfway the minimum and maximum value of interventricular asynchrony as well as the QRS vector.

Study objective

The aim of the present study is to investigate whether the relation between QRS vector, interventricular asynchrony and improvement in LV pump function is present in CRT patients. Subsequently, we want to show that the QRS vector can be used as a non-invasive and simple tool to optimize the configuration of the

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BiV pacing device resulting in best hemodynamic improvement.

Study design

This study comprises an acute validation study, investigating QRS vector analysis for optimization of BiV pacing in CRT patients by programming the best suitable AV and VV delay.

Study burden and risks

During the proposed pacing protocol patients are exposed to a little physical discomfort, because they have to lie down for approximately two hours. No significant risks are identified and no psychological discomfort is associated with participation.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

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Elderly (65 years and older)

Inclusion criteria

For patients with cmplete AV-block (n <= 20) * Absence of AV conduction * Sinus rhythm * BiV device implanted <2 years ago;For patients with LBBB (n <= 20) * Complete LBBB (QRSd >150ms) * Sinus rhythm * BiV device implanted <2 years ago

Exclusion criteria

- * Ischemic heart disease <6 months
- * Insufficient image-quality of echo
- * Complete AV-block or permanent atrial fibrillation for the LBBB group

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	40
Туре:	Actual

Ethics review

Approved WMO

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Date:	19-01-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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 CCMO **ID** NL33605.068.10