E-pot Study: EnSite & Pressure- Volume in Cardiac Resynchronization Therapy, a multicenter, prospective, feasability, non-randomized pilot study

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

Summary

ID

NL-OMON32196

Source
ToetsingOnline

Brief title
E-pot study

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 BV Nederland

Intervention

Keyword: CRT-D, EnSite, Optimisation, PV-loop

Outcome measures

Primary outcome

Optimal position of the lead is defined as the one providing optimal acute hemodynamics (defined by the highest Stroke Volume as measured by Pressure-Volume recordings compared to Atrial paced-Ventricle sensed pacing configuration)

Secondary outcome

1. Assessment of the correlation between the electrical activation pattern and Stroke Work.

2. Assessment of the correlation between mechanical delay and electrical delay. The mechanical (resp. electrical) delay will be defined as the maximum delay between the first and the last contracted (resp. activated) area.

3. Assessment of correlation between scar tissue areas and the latest electrical and mechanical activated areas

4. Assessment of correlation between dp/dt & volumes (PV loops recordings) and optimal position of pacing wire

5. Assessment of electrical parameters: correlation between QRS width and electrical activation patterns

Study description

Background summary

Today it is relatively well accepted that cardiac resynchronization therapy improves hemodynamic parameters, exercise capacity, symptoms, and quality of life and also reduces hospitalization among patients with severe heart failure, impaired LV function and widened QRS complex usually with a left bundle branch block. Devices that combine biventricular pacing with an implantable defibrillator have moreover demonstrated a significant reduction in arrhythmic death in high-risk population.
The responsible mechanisms are believed to include improved synchrony of the timing of left and right ventricular (RV) systole (interventricular synchrony), improved synchrony of the different segments of the left ventricle (intraventricular synchrony), and a reduction in mitral regurgitation.
However, it was noted that 25% to 30% of patients did not respond to CRT, emphasizing the need for better selection criteria. In this frame, the resynchronization of pre-existent LV dyssynchrony is considered a major player in determining the response to CRT [Yu, Bax]. Indeed detailed echocardiographic assessment using tissue Doppler echocardiography showed that patients with left bundle-branch block (LBBB) have marked intraventricular dyssynchrony that can be improved by biventricular pacing. [Yu Circ 2002].
Another potential reason for non-response to CRT (in patients with ischemic cardiomyopathy) may be the presence of extensive scar tissue in the region of the tip of the LV pacing lead [Bleeker et all Circ 2007]

Study objective

The main objective of this study is:
• To determine the optimal site to position the left ventricular pacing lead for each individual patient with an ischemic Cardiomyopathy (CMP). The site is selected based on the latest mechanical activated site and the latest electrical activated site, whatever pacing configuration tested.
• To assess changes in activation pattern and the hemodynamic effects due to (single- or dual-site) left ventricular and biventricular pacing.

The following objectives will also be assessed:
• The relationship between the electrical and mechanical delay.
• The relationship between scar characteristics and the latest electrical and mechanical areas activated

Study design

This clinical trial is a multicenter, prospective, feasibility, non-randomized pilot study.
All patients taking part in this study will undergo the implantation of a CRT-D device with transvenous leads. After successful implantation and after hospital discharge, patient will be followed for 6 months after implant. The invasive

part of the study contents two phases where in phase I endocardial mapping and PV-loop measurements are performed. In phase II the device will be implanted at the pre-defined optimal lead position(s) and pacing configuration.

Patients will attend protocol scheduled visits before implant (pre-implant evaluation), and post-implant: pre-hospital discharge and at 6 months.

Study burden and risks

There is a mild extra risk in concordance to the regular diangnostics in patient with inschemic heartfailure, as MRI, echocardiography and electrophysiologic evaluation. During the first invasive fase Pressure-volume loops are measurend using a conductance catheter in the left ventricle. The risk of left ventricular catherization is similar to regular evaluation of coronary arteriography in patients with coronary artery disease.

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

• CRT-D conventional indication
• QRS width > 120 ms
• Left Ventricular Ejection Fraction (LVEF) < 35%.
• Left Bundle Branch Block (LBBB)
• MI documented by echo or MRI
• Cardiomyopathy stable for the last Month (or longer)
• Pharmacological treatment unchanged during the 3 last Months (or longer)
• Heart failure NYHA class II & III

Exclusion criteria

• History of chronic AF
• MI within the last 3 Months
• Previous pacemaker or ICD implanted
• Claudication intermittens or other significant arterial vein issues in the aortic-iliac route
• Moderate to severe aortic valve stenosis or indication for valve surgery or mechanical aortic valve replacement or thrombus in Left Ventricle
• Age <18 years or > 80 years
• Heart failure NYHA class IV
• Serious comorbidity such as cancer, with a likelihood of death during the study
• Unwilling or unable to sign the consent form for participation
• Females of childbearing age not using medically prescribed contraceptives

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-11-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL22366.075.08