Effects of left ventricular pacing optimalisation on cardiac perfusion, contractile force, and clinical performance in patients with ventricular dysfunction and heart failure

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To compare a surgical approach with the conventional transvenous approach by assessment of differences on the effects on cardiac perfusion and relate this to the clinical cardiac function.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON31055

Source
ToetsingOnline

Brief title
CONTRACT

Condition

- Heart failures

Synonym
congestive heartfailure, heartfailue

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac resynchronisation therapy, coronary sinus, epicardial lead

Outcome measures

Primary outcome

Degree of change in cardiac perfusion abnormalities and the relation to cardiac function.

Secondary outcome

Determination of the diagnostic value of TDI, 2D- and 3D-echocardiography to predict the optimal site of LV stimulation in BIV paced patients to support and optimize pacing therapy.

Change in clinical status.

Improvement of NYHA classification.

Difference in QRS duration on the ECG.

Improvement of 6MWT.

Improvement in QOL score.

Changes in biomarkers (ANP, and pro-BNP).

Determination of the feasibility of epicardial LV lead placement at the site of maximum dyssynchrony.

Study description

Background summary

Resynchronisation therapy has shown to reduce mortality and improve morbidity. During biventricular pacing, optimal LV lead placement is crucial to achieve a maximum effect. LV lead placement through the conventional transvenous route is often hampered by unfavourable coronary sinus anatomy and diaphragm stimulation. Furthermore this approach is time-consuming and performed using prolonged fluoroscopy times. Often, a sub-ideal lead position is accepted and further extensive attempts are aborted. Surgical epicardial LV lead placement at a position anticipated being the optimal site (with maximal dyssynchrony) as measured by preoperative tissue Doppler imaging may be a more favourable approach. This may be expressed by a better myocardial perfusion.

Study objective

To compare a surgical approach with the conventional transvenous approach by assessment of differences on the effects on cardiac perfusion and relate this to the clinical cardiac function.

Study design

This study is designed as a randomised, single-centre, open-label trial, with a minimum of 26 patients in each group. Patients included have a clear indication for resynchronization therapy. After randomization a biventricular ICD is implanted. To analyse changes in clinical parameters, baseline data are collected derived from the patient*s history, physical examination, NYHA classification, ECG, laboratory testing with assessment of biomarkers such as ANP/pro-BNP, 6-minute walk testing (6MWT), quality of life questionnaires (QOL), 2D- and 3D echocardiography, and findings on SPECT. These data are repeated during follow-up (at 3 and 6 months). The study is completed as soon as the inclusion is complete 6 months after the last patient is included.

Intervention

Implantation of a biventricular pacemaker, with or without ICD-function. Depending on the randomization, a transvenous os surgical epicardial placement of the LV lead is performed.

Study burden and risks

3 visits to the outpatient clinic ar expected of every patient, at baseline and at 3 and 6 months after implantation. During this visits, physical examination, NYHA classification, ECG, laboratory testing, 6-minute walk testing (6MWT), quality of life questionnaires (QOL), 2D- and 3D echocardiography and SPECT are performed.

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

Heart failure, New York Heart Association (NYHA) class III or IV
QRS-duration >120 ms, or when paced > 200 ms on 12-lead ecg
left bundle branch block on ecg
LVEF at most 35%
Dyssynchrony on echocardiography
Optimal medical treatment for congestive heart failure

Exclusion criteria

Age < 18 years
Severe heart failure with life expectancy < 6 months

Permanent or persistent atrial fibrillation
Indication for cardiac surgery within 6 months
Life expectancy < 1 year
Contraindications for anesthesia
Participation in another clinical trial
Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-09-2008
Enrollment:	52
Type:	Actual

Medical products/devices used

Generic name:	ICD with biventricular pacemaker
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-11-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	21-03-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL17793.100.07
Other	RDC-2006-04