Hemodynamic Cardiac Profiler for Assessment of Acute Hemodynamic Changes in Heart Failure Patients Undergoing Cardiac Resynchronization Therapy

Published: 22-01-2021
Last updated: 08-04-2024

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

Summary

ID

NL-OMON55084

Source
ToetsingOnline

Brief title
HEMOCART

Condition

- Heart failures

Synonym
Chronic Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Hemologic bv.

Intervention

Keyword: (CRT) Cardiac Resynchronization Therapy, Heart Failure, Hemodynamic Cardiac Profiler, Hemodynamic Changes

Outcome measures

Primary outcome

Volume-time curves obtained during various pacing configurations will be compared between the non-invasive method (HCP) and the invasive method (conductance catheter).

Secondary outcome

1. Evaluate derivatives of volume-time curves (i.e. stroke volume, max volume, min volume, 1/3 FFR) and compare these derivatives between different pacing settings and between the HCP volume-time curve and conductance catheter volume-time curve.

2. Assessment of pressure data during different pacing settings and comparison between the invasive pressure measurements (conductance catheter) and the non-invasive pressure measurements (Nexfin)

3. Reconstruction of pressure-volume (PV) loops with Nexfin and HCP data and compare these PV- loops with PV-loops obtained using the conductance catheter.

Study description

Background summary

Cardiac resynchronization therapy (CRT) is an effective therapy for heart failure patients with electromechanical ventricular dyssynchrony. Device optimization can be achieved by invasive pressure-volume measurements and unfortunately robust non-invasive alternatives are currently lacking. The Hemodynamic Cardiac Profiler (HCP) can measure left ventricular (LV) stroke volume using ventricular field recognition by applying six electrode pairs over the frontal thoracic skin. Combining this novel non-invasive method with non-invasive pressure measurements (Nexfin) might be promising for CRT device optimization.

Study objective

The objective of this study is to assess the feasibility of HCP measurements in CRT patients during different pacing settings. We will evaluate the accuracy of LV volumetric measurements in patients with an implanted CRT. For this evaluation, LV volumes and the effects of biventricular pacing on LV function will be related to *the gold standard* invasively assessed changes in LV pump function with the conductance catheter.

Study design

Prospective observational study with invasive measurements, implemented after CRT implantation.

Intervention

CRT candidates will receive device optimization and simultaneous study measurements directly after device implantation. Patients will undergo invasive pressure-volume (PV) loop assessment during various biventricular pacing settings to obtain functional and volumetric measurements. In addition, the optimal stimulation configuration will be programmed in the device which benefits the patient. Simultaneously, measurements with the HCP (volumes) and Nexfin (pressures) will be performed to assess feasibility and compare the non-invasively achieved data with the invasively achieved data.

Study burden and risks

The introduction of non-invasive CRT optimization techniques to study the effects of CRT might result in better understanding of underlying mechanisms. Ultimately this might improve CRT benefit. Participation in this study requires an additional invasive procedure. This procedure will be scheduled directly after device implantation. The patients will have direct benefit from the invasive procedure, since patient specific optimal device settings will be assessed and programmed in the device.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients need to fulfil the 2013 guideline of the European Society of Cardiology criteria for cardiac pacing and cardiac resynchronisation therapy upon receiving a CRT.

Exclusion criteria

Age <18
Frequent extrasystole (more than 10%)
Artificial aortic valve or aortic stenosis
LV volume > 300 ml
Other implantable devices than CRT/PM/ICD in the upper body

Structural anatomical / congenital cardiac *deviations*

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):	26-02-2021
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Haemodynamic Cariac Profiler
Registration:	No

Ethics review

Approved WMO

Date:	22-01-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL72894.029.20