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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20610

Source
NTR

Brief title
HEMOCART

Health condition

Heart failure

Sponsors and support

Primary sponsor: VUmc
Source(s) of monetary or material Support: Hemologic bv

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to assess clinical feasibility and accuracy of HCP measurements in CRT patients during different pacing settings. We will evaluate the accuracy of LV volumetric measurements by comparing volume-time curves obtained using HCP with the conductance catheter (gold standard) measurements.

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. Unfortunately, robust non-invasive alternatives are currently lacking. The Hemodynamic Cardiac Profiler (HCP) can measure left ventricular (LV) stroke volume non-invasively 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 might allow non-invasive CRT device optimization.

Study objective

We hypothesise that HCP provides reproducible and accurate measurements of LV volume changes during different CRT pacing settings which are comparable with invasive conductance catheter measurements.

Study design

1 (invasive and non-invasive measurements on the cath-lab using the conductance catheter, HCP and Nexfin)

Intervention

Invasive and non-invasive volume measurements

Contacts

Public
VUmc
Luuk Hopman

0204441405
Scientific
VUmc
Luuk Hopman

0204441405

Eligibility criteria

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:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-03-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-03-2021
Application type:	First submission

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
NTR-new	NL9375
Other	METC VUmc : 2020.441

Study results