Optimizing cardiac resynchronization therapy with the use of an implantable heart monitor

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

Summary

ID

NL-OMON42377

Source
ToetsingOnline

Brief title
Optimizing CRT with IHM

Condition

- Heart failures

Synonym
heart failure / pump failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CRT, Implantable heart monitor, Optimizing

Outcome measures

Primary outcome

The primary study outcome will be the dataset collected by the hartmonitor during the conventional, invasive, pressure guided (dP/dt) optimalisation of the resynchronisation device. Which should lead to a usable algorhytm for optimizing resynchronisation pacing only using the hartmonitor in the futur.

Secondary outcome

Not applicable.

Study description

Background summary

Cardiac resynchronization therapy (CRT) has become common practice in patients with drug refractory heart failure (HF) and cardiac asynchrony. Unfortunately, approximately one third of the recipients of a CRT-device are non-responders. Optimization of the device helps to improving the number of responders. Measurement of changes in pressure over time (dP/dt) of the left ventricle is still the gold standard for optimization of CRT-devices. However, invasive dP/dt measurements are complicated, time-consuming, costly and foremost not without risk for the patient. Therefor there is a need for a non-invasive tool for recurrent optimization of CRT-devices.

Study objective

In a pilot study patients scheduled for a regular implantation of a (or undergoing an upgrade to a) CRT-device will also be implanted with a heart monitor in the pulmonary artery. This implantable heart monitor (IHM) will collect data during optimization of the CRT-device. Subsequently, the dataset collected by the implantable heart monitor (IHM) will be used to determine the IHM-read out associated with an optimal dP/dt during CRT-optimization.
The aim of the pilot study is to establish if, and so how an IHM can be used

for optimization of CRT-devices.

Study design

The present study is a 'pilot study' used as a proof of principle.

Study burden and risks

Potential issues of concern
Both the CRT-devices and the CardioMEMS sensor are indicated for use in the proposed patient population. The risks and benefits are well known and not under examination in the present study. Further information can be found in the IBs of these devices. Optimizing CRT-devices is also part of our common day clinical practice and using a pressure wire for this is still the golden standard and used often. However an optimization is not always performed and in some clinics this is only done on indication, i.e. cardiac underperformance after CRT-implant. Therefor it could be argued that the explicit optimization is a potential concern. Collecting the CardioMEMS sensor data during the optimization holds no risks or extra burden to the participants and it does not prolong the optimization. Therefore, the risk analysis will focus on the optimization itself as it will be performed as standard care in all participants of the study and not only on indication as is also common.
To be able to perform the invasive optimization a temporary pressure wire has to be placed in the left ventricle. This is done using conventional fluoroscopy and it is estimated to take approximately 5 minutes. This amounts to 5 mSv per participant which is a category IIb (= 1 to 10 mSv) or intermediate risk in accordance with the ICRP62.

Previous experiences with invasive optimization
These kinds of optimizations usually take 1 hour, are performed at the cathlab and during which the patient has to lie down on the treatement table while the measurements take place. The measurements are done using a small pressure sensitive catheter introduced through the femeral artery into the left ventricle.
The adverse event with the highest incidence one can expect is a hematoma at the excess site. Similar studies showed an incidence of 3% of groin hematomas, i.e. 1 in 33 patients.[Duckett SG, Ginks M, Shetty AK, Bostock J, Gill JS, Hamid S, Kapetanakis S, Cunliffe E, Razavi R, Carr-White G, Rinaldi CA. Invasive acute hemodynamic response to guide left ventricular lead implantation predicts chronic remodeling in patients undergoing cardiac resynchronization therapy. J Am Coll Cardiol. 2011;58:1128-36] Our own registry at the AMC of procedures utilizing the blood vessels in the groin shows an incidence of 2% for all groin complications. These kind of adverse events are usually treated conservatively with local pressure bandage. In the worse cases the interventional radiologist is asked to close ongoing bleeding, AV-fistulae or aneurysms using thombin injections. And if even these measures are unsuccessful

one can imagine that the vascular surgeon has to be consulted.
One can speculate that assuming a supine position on the operating table, combined with the stress and anxiety for the procedure could cause extra strain of the heart. This could induce acute heart failure that would require medical treatment. In our complication registry of pacemaker and ICD implantations this was seen once in the past year, i.e. 1 in 473 patients, amounting to an incidence of 0.2%.
Other adverse events have an even lower incidence. However, one can imagine that every time you put a wire though arteries and in to the left ventricle one could damage the blood vessels or even the heart itself. Studies dealing with dP/dt measuring have not encountered these kind of problems. Although empirically this does not seem to be a problem it can imagined that patients whose myocardium is pierced by the pressure wire suffer a tamponade. The lion*s share of cases of tamponade is treated conservatively or if necessary by putting a small transcutaneous catheter in the pericardial space until the tamponade is resolved spontaneously. To the best of my knowledge there had never been a tamponade in the AMC caused by a dP/dt measurement.

Potential benefits
Potential benefits for implanting CRT-devices is common knowledge, the same goes for the addition of optimization. The potential benefit of implanting the CardioMEMSTM sensor is twofold. First, the sensor can be used as the early warning system of HF for which it was designed. Second, if the pilot is successful the sensor could be used repeatedly to optimize the CRT-device without any invasive, lengthy and elaborate procedure with pressure wires.

In summary
The risk for adverse events caused by doing dP/dt measuring on a structural basis instead of only on indication is very limited. Moreover, to reduce this small risk even further, all measurements will be done under strict observation using ECG-, blood pressure and oxygen saturation monitoring, performed at our fully equipped cathlab. Furthermore, there does not seem to be an alternative for the present study. Finally, the reward (i.e. the development of a reliable, usable and reusable, non-invasive optimization tool) seem to outweigh the minimal risk involved in the study.

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

*Class I or IIa criteria of the 'European Society of Cardiology' for cardiac resynchronisation.
*Class III heart failure according to the 'New York Heart Association' with a hospitalization for hartfailure in the previous year.
*Willing and able to understand and comply with the study requirements and providing a signed informed consent.

Exclusion criteria

*Under aged.
*Pregnant.
*Expected to undergo cardiac surgery in the near future.
*Permanent atrial fibrillation.
*Already having a cardiac resynchronisation device implanted previously.
*Pulmonary embolism in the prior 6 months or repeatedly in their lifetime.
*Cerebrovascular incident (CVA or TIA) in the previous 6 months.
*History of clotting or bleeding disorders (i.e. hyper- and hypocoagulability).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Optimizing cardiac resynchronization therapy with the use of an implantable heart monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-07-2015
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	NL52966.018.15