ReachPR Trial: Restoration of AV coupling by Cardiac Resynchronization Therapy in heart failure patients with prolonged PR interval

Published: 14-12-2017
Last updated: 15-02-2024

The purpose of this study is to investigate the acute hemodynamic effects of restoration of AV coupling by atrio-biventricular pacing in patients with HF and prolonged PR interval.

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

Summary

ID

NL-OMON53332

Source
ToetsingOnline

Brief title
ReachPR Trial

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,St. Jude Medical

Intervention

Keyword: Atrioventricular dyssynchrony, Cardiac resynchronization therapy, Heart failure, Prolonged PR interval

Outcome measures

Primary outcome

The acute hemodynamic changes in LV stroke work (SW) during AV optimization by atrio-biventricular pacing.

Secondary outcome

- The acute hemodynamic changes in LV dP/dt|max and LV stroke volume (SV) by invasive measurements during AV optimization by atrio-biventricular pacing.

- The acute hemodynamic changes in LV stroke volume (SV), diastolic mitral regurgitation and LV diastolic filling time by echocardiography during AV optimization by atrio-biventricular pacing.

Study description

Background summary

Prolongation of the electrocardiographic PR interval (PR interval > 200ms; also known as first-degree atrioventricular block) is frequently encountered in clinical practice and is generally considered as a benign sign. However, there is increasing evidence that a prolonged PR interval results in poor hemodynamic performance with elevated left ventricular (LV) end-diastolic pressures evidenced by diastolic mitral regurgitation. Previous studies also associated a prolonged PR interval with a substantially increased risk of future atrial fibrillation (AF) and pacemaker-implantation, and increased risk of heart failure (HF) hospitalization and death. These risks stress the importance of proper atrioventricular (AV) coupling. Shortening of the PR interval may be especially important in HF patients. Shortening of the PR interval can be obtained by AV pacing. A possible adverse effect of ventricular pacing is that it results in ventricular dyssynchrony possibly leading to worsening cardiac function. This effect may be prevented by applying atrio-biventricular pacing.

Data from several previous (sub)studies suggested this.

Study objective

The purpose of this study is to investigate the acute hemodynamic effects of restoration of AV coupling by atrio-biventricular pacing in patients with HF and prolonged PR interval.

Study design

This study will be a multi-center, exploratory, prospective interventional, non-randomized acute hemodynamic study, using patients as their own controls.

Intervention

Extra hemodynamic measurements will be performed during CRT implantation (invasive) and after approximately one to two weeks (echocardiographic protocol).

Study burden and risks

The patients are candidates for an ICD device in whom cardiac resynchronization therapy (CRT) can be considered according to current guidelines. Patients in the present study will receive a CRT-defibrillator (CRT-D). The risk and/or complications of the CRT-D implantation are not additional for this study. After the implantation, acute invasive hemodynamic measurements will be performed with a pressure-volume catheter, which is inserted via the femoral artery and adds approximately 30 minutes to the standard procedure. We need an extra radiation dose of approximately 50mGy to place the pressure-volume catheter in the LV cavity. Local vascular complications of femoral artery puncture like bleeding or damage to the vessel wall may occur but are rare. The non-invasive echocardiographic protocol one to two weeks after implantation will add approximately 45 minutes to the routine outpatient clinic visit. The patients don*t have to visit the clinic outside the routine outpatient clinic visits before and after a CRT-D implantation. The patients will have the potential direct benefit from the procedure, by finding the patient*s specific optimal (AV) settings and thereby reducing above described risks of a prolonged PR interval. In case of a worse hemodynamic performance due to the procedure, the CRT-D will be programmed to back up pacing and there is no harm for the patient outside the above subscribed extra measurements.

Contacts

Public

Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

Eligibility criteria

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

Inclusion criteria

- Indication for an ICD device according to current guidelines;
- Stable prolonged PR interval >230ms;
- Reduced LVEF (< 35%);
- New York Heart Association (NYHA) functional class II, III or ambulant IV;
- Stable sinus rhythm (no documented AF-episodes during the last 4 weeks prior to inclusion);
- Optimal heart failure (oral) medication, and on a stable medication scheme at least 1 months prior to enrolment
- Age * 18 years and < 80 years.

Exclusion criteria

- Already implanted with an CRT device;
- Resting Heart rate >90 bpm;
- LBBB QRS morphology;
- QRS duration >150ms
- Recent myocardial infarction (within 40 days prior to enrolment);
- Second or third degree AV block;
- Life expectancy < 1 year.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-06-2018
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL60764.068.17