Acute cardiac resynchronization therapy for right ventricular disease

Published: 27-05-2008
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To attenuate the clinical severity of right ventricular disease by electrical pacing

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

Summary

ID

NL-OMON32199

Source
ToetsingOnline

Brief title
Resynchronization therapy for right ventricular disease

Condition

- Heart failures

Synonym
pulmonary hypertension

Research involving
Human

Sponsors and support

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

Intervention

Keyword: pulmonary hypertension, resynchronization, right ventricular disease

Outcome measures

Primary outcome

Primary: the reduction (in msec) of right-to-left delay in onset of diastole

following acute CRT as measured using tissue Doppler echocardiography.

Secondary outcome

Secondary: the improvement (in l/min) of cardiac output following acute CRT as

measured using pressure-conductance measurements in the left ventricle and

noninvasive FinaPress*, and the improvement of microcirculation following acute

CRT as measured using noninvasive SDF.

Study description

Background summary

Right ventricular disease has increasing clinical relevance, because it affects a growing number of patients. Yet, effective therapies are lacking. We have recently established that the clinical severity of right ventricular disease is largely determined by electrical interventricular dyssynchrony, i.e., delay of electrical activity between the right and left ventricles. In this study, we aim to establish whether acute correction of this dyssynchrony by temporary electrical pacing attenuates the clinical severity of right ventricular disease

Study objective

To attenuate the clinical severity of right ventricular disease by electrical pacing

Study design

Acute intervention study

Intervention

acute cardiac resynchronization therapy (CRT), i.e., temporary right atrial and

right ventricular pacing immediately after routine right heart catheterization

Study burden and risks

Acute CRT will take 30-45 min (including the associated assays such as tissue Doppler echocardiography, FinaPress*, and SDF) and will be conducted immediately after routine right heart catheterization and coronary angiography in the catheterization room. Thus, the subject will undergo an additional 30-45 min of study. Based on our extensive experience with temporary cardiac pacing in the catheterization room, we do not expect adverse events form this study. We do not aim for immediate benefit for the subject, because this study entails temporary CRT. However, these studies can only be conducted in this patient group (CTEPH) patients, because we have established the pathophysiological basis and rationale of this study in this patient group. It must be noted that chronic CRT may be considered in these patients if the present study should prove successful. Chronic CRT may benefit CTEPH patients, in particular, those who are ineligible for pulmonary endarterectomy or in whom pulmonary endarterectomy has not resulted in improved functional class.

Contacts

Public
Academisch Medisch Centrum

AMC, Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

AMC, Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult CTEPH patients who undergo right heart catheterization to obtain hemodynamic data as part of the regular diagnostic workup to assess their eligibility for pulmonary endarterectomy

Exclusion criteria

none

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL21560.018.08