Acute cardiac resynchronization therapy for chronic thromboembolic pulmonary hypertension

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

Summary

ID

NL-OMON32814

Source
ToetsingOnline

Brief title
Acute CRT for CTEPH

Condition

- Heart failures

Synonym
pulmonary hypertension, right ventricular 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: cardiac resynchronization, pacing, pulmonary hypertension, right ventricular failure

Outcome measures

Primary outcome

Reduction (in msec) of right-to-left delay in onset of diastole following acute

CRT as measured using tissue Doppler echocardiography.

Secondary outcome

Improvement (in l/min) of cardiac output following acute CRT as measured using

Doppler echocardiography.

Study description

Background summary

The clinical severity of right ventricular disease is largely determined by right-to-left ventricular dyssynchrony, i.e., delay of electrical activity between the right and left ventricles. Moreover, in patients with chronic thromboembolic pulmonary hypertension (CTEPH), we found that acute correction of this dyssynchrony by temporary pacing during routine preoperative (i.e., prior to pulmonary endarterectomy, the best therapy for CTEPH) cardiac catheterization results in significant improvement in cardiac output.

Study objective

In this study, we aim to establish whether temporary pacing is also effective in CTEPH patients who are not eligible for pulmonary endarterectomy, or those in whom pulmonary endarterectomy has failed. These severely symptomatic patients, for whom no effective therapy exists, potentially benefit greatly from this novel therapy: if temporary pacing should prove effective, future studies may test the efficacy of chronic pacing (with implanted pacemakers).

Study design

Acute intervention study.

Intervention

Acute cardiac resynchronization therapy (CRT), i.e., temporary right atrial and right ventricular pacing.

Study burden and risks

Acute CRT will be conducted in the catheterization room with the use of 2 pacing catheters (in the right atrium and the right ventricle apex), inserted into the femoral vein under local anaesthesia. This is a standard configuration for electrophysiologic studies, that we conduct routinely. We therefore do not expect adverse events from this study. The whole procedure will take 60-90 min. These studies can only be conducted in this patient group (CTEPH patients), because we have established the pathophysiological basis and efficacy of CRT in this patient group. Chronic CRT may be considered in those patients in whom acute CRT in the present study improves cardiac output.

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

1) adult (>18 years) CTEPH patients
2) New York Heart Association functional class III or IV
3) right-to-left delay >40ms (assessed with previously conducted echocardiographic measurements)

Exclusion criteria

inability to provide informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	temporary pacing
Registration:	Yes - CE intended use

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	NL30418.018.09