Imaging of Ventricular Reversed Remodeling after Double Lung Transplantation in Patients with Pulmonary Arterial Hypertension

Published: 23-07-2014
Last updated: 20-04-2024

To study remodeling patterns of the left and right ventricle in patients with pulmonary arterial hypertension who underwent lung transplantation, using cardiac magnetic resonance imaging.

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

Summary

ID

NL-OMON41137

Source
ToetsingOnline

Brief title
Ventricular reversed remodeling after LTX in patients with PAH

Condition

- Heart failures
- Pulmonary vascular disorders

Synonym
high blood pressure pulmonary artery, Idiopathic/primary pulmonary arterial hypertension

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac Magnetic Resonance Imaging, Lung transplantation, Pulmonary Arterial Hypertension, Right Ventricle

Outcome measures

Primary outcome

Right ventricular remodeling measured on cardiac magnetic resonance (CMR) imaging after LTX will be investigated in terms of: 1) RV mass, trabecularisation and extracellular matrix composition; 2) geometry and septal configuration; 3) radial, circumferential and longitudinal deformation. Left ventricular remodeling comprises function, geometry and mass.

Secondary outcome

Functional parameters on echocardiography, disease specific electrophysiological findings on electrocardiography (ECG) and N-terminal probrain natriuretic peptide (NT pro-BNP) level.

Study description

Background summary

Pulmonary arterial hypertension (PAH) is a fatal disease characterized by right ventricular (RV) dysfunction and failure. Right heart catheterization (RHC) is the golden standard for PAH diagnosis. However, over the years, cardiac magnetic resonance (CMR) has evolved in an excellent non-invasive tool for the assessment of major functional parameters that are frequently associated with increased pulmonary artery pressure. Today, CMR is complementary to RHC in the follow-up of patients with PAH. Furthermore, CMR by itself is of potential importance in evaluating PAH-targeted therapies.

Current therapies for PAH have improved long-term outcome, although mortality remains high. For patients refractory to medical therapy, lung transplantation (LTX) is often indicated as destination therapy. Several studies investigated functional outcome after LTX. However, these studies are outdated, used invasive measurements and lack CMR assessment. Exploration of biventricular remodeling after double-LTX in patients with PAH, using CMR, could be of potential importance in the timing of surgical intervention and may elucidate RV and LV functional recovery after long standing pulmonary hypertension and pressure unloading.

Study objective

To study remodeling patterns of the left and right ventricle in patients with pulmonary arterial hypertension who underwent lung transplantation, using cardiac magnetic resonance imaging.

Study design

Explorative case study

Study burden and risks

The following assessments will be performed twice in each patient (i.e. preoperative and six months postoperative):
- Past and present medical history: including NYHA-functional class.
- Physical examination: including length and weight.
- CMR (for LV and RV volumetric and mass analysis and extracellular matrix composition [i.e. T1-mapping]).
- Transthoracic echocardiography (TTE, standard protocol for chamber quantification; function of valves; pulmonary artery systolic pressure; if applicable other disease-specific assessments).
- Resting ECG: for the assessment of disease specific electrophysiological findings.
- Laboratory evaluation: NT-pro-BNP, eGFR (remaining serum will be stored).

In all patients, laboratory evaluation, echocardiography and ECG are part of the routine follow-up before and after LTX. In order to store serum for biomarker analyses in the future, three extra blood samples (10 ml each) will be obtained during the already planned vena-puncture.

In patients with PAH, preoperative and postoperative CMR are part of the standard investigations.

In the control patients (i.e. no pressure load of the RV), preoperative and postoperative CMR are not part of the standard investigations.

All investigations will be scheduled in combination with already planned visits to the clinic. Therefore, participation in this study will expose the patients to a minimum amount of extra effort. Patients who participate in this study will be exposed to known risks and side effects of gadolinium-based contrast agent during CMR.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Primary study group:
- Patients who are on the waiting list for double-LTX, in our institution, for pulmonary arterial hypertension
- Eligible for CMR imaging
- No claustrophobia

- No pacemaker, ICD, etc.
- Informed consent;Control group:
- Patients who are on the waiting list for double-LTX, in our institution.
- Echocardiographic evaluation including an estimation of RV peak pressure, <35 mmHg.
- Eligible for CMR imaging
- No claustrophobia
- No pacemaker, ICD, etc.
- Informed consent

Exclusion criteria

- Inability to comply with primary endpoint measures.
- Body mass index >40 kg/m2.
- Pregnant patients will not be included, they may be included >3 months after pregnancy.
- Patients with age <18 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL48555.042.14