# Multi-detector CT coronary angiography in the work-up of potential candidates for lung transplantation.

Published: 17-01-2011 Last updated: 04-05-2024

1. To assess the feasibility of performing CT coronary angiography in potential candidates for lung transplantation. 2. To assess the accuracy, especially the negative predictive value, of CT coronary angiography in the detection of both significant...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

# Summary

### ID

NL-OMON34430

**Source** ToetsingOnline

**Brief title** CT coronary angiography in lung transplantation screening

# Condition

• Coronary artery disorders

Synonym Coronary bloedcirculation

**Research involving** Human

# **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W

#### Intervention

Keyword: angiography, coronary, lung transplantation., Multi-detector CT

#### **Outcome measures**

#### **Primary outcome**

The main study parameter will be the accuracy, especially the negative

predictive value, of CT coronary angiography as compared to conventional

angiography.

#### Secondary outcome

To evaluate the feasibility to perform CT coronary angiography in potential

candidates for lung transplantation.

# **Study description**

#### **Background summary**

Since the first lung transplantation in man in 1963 (1), several thousands of lung transplantations have been performed and lung transplantation is now a generally accepted therapy for the management of a wide range of end stage lung diseases. In 1998, the first edition of the International Guidelines for the Selection of Lung Transplant Candidates was developed which was updated in 2006 (2). These guidelines assist physicians worldwide in referring potential candidates for lung transplantation. Absolute and relative contraindications are considered as well as factors that may be of importance in the decision to refer patients to a lung transplantation clinic but also to list and potentially (sometimes temporally) de-list lung transplant candidates as well. Selection criteria for placement on the active waiting list for lung transplantation vary between centres, but the presence of more than 1 significant (luminal reduction >50%) coronary artery disease (CAD) is traditionally considered an absolute contraindication for lung transplantation since this may limit survival after transplantation. Diffuse CAD with non-significant stenoses (luminal reduction < 50%) or isolated significant stenosis (luminal reduction > 50%) is considered a relative contraindication for lung transplantation. In patients with limited CAD (single-vessel disease and good left ventricular function) lung transplantation has recently been performed in combination with cardiac surgery with good results (3), and even

in patients who underwent bypasses for 2- and 3-vessel disease (4). Therefore, the assessment of potential coronary artery disease remains an important part of the routine workup of potential lung transplantation candidates. The true incidence of CAD in patients considered candidates for lung transplantation is not known. However, many of these patients with end-stage lung disease also have a significant smoking history. Consequently, conventional coronary angiography is often routinely performed as part of the lung transplantation screening program in patients over 40 years (or 50 years, depending on the local protocol). In a study of 118 lung transplantation candidates > 40 years who underwent coronary angiography, significant CAD (luminal reduction >= 70% in diameter) was found in 21 patients (18%) (5). In another study, in which coronary angiography was performed in 101 candidates > 50 years, an incidence of 17% of significant CAD was found (6). In our hospital, 30 patients are screened yearly for lung transplantation. Two thirds of the patients screened for lung transplantation are > 40 years and undergo coronary angiography, and 20% had CAD (unpublished data). This is in good agreement with the literature.

Conventional coronary angiography is the gold standard to exclude significant and non-significant CAD, but the procedure is invasive, relatively costly and may result in patient morbidity. Although the frequency of serious complications (such as significant bleeding, heart and lung problems including heart failure, stroke, heart attack and local damage to organs, nerves and blood vessels) is low, it is not insignificant. In addition, access site vascular complications (e.g., femoral hematoma, arterial pseudoaneurysm, fistula) are a well-described risk of coronary angiography with an incidence of 1-6% of all catheterizations (7).

Multi-detector Computed Tomography (CT) coronary angiography has emerged as a non-invasive patient-friendly imaging modality that permits evaluation of both the coronary lumen and coronary vessel wall (8-13). Recent developments in multi-detector CT technology have resulted in a markedly improved resolution when compared to earlier CT scanner generations. Current state-of-art 64-slice CT scanners offer high quality, nearly motion-free, isotropic image quality in patients with a low (<70 beats/minute) and stable heart rhythm (8-13). The diagnostic performance to detect significant obstructive lesions (>50% luminal diameter stenosis) is high. The sensitivity, specificity, positive and negative predictive values are 90%, 94%, 70% and 95% respectively (8-13). However, previous studies using 16- and 64-slice CT scanners have shown an inverse relationship between heart rate and image quality concerning coronary artery visualization and stenoses detection (14, 15). Consequently, in order to achieve a high accuracy in the detection of coronary artery stenosis, the heart rate is usually lowered to <65-70 beats/min using pre-medication such as beta-blockers or nitro-glycerine. Patients screened for lung transplantation frequently have basal heart rates as high as 90-100 beats/min. However, beta-blockers are contra-indicated in patients with bronchial hyperactivity (e.g., asthma), COPD patients on beta agonist therapy and pulmonary arterial hypertension (PAH) whereas nitro-glycerine is contraindicated in PAH patients. Alternative drugs such as Ivabradine are available and can be safely used in

most patients.

The most recent dual-source CT scanners and 128-slice or even 256- and 320-slice CT scanners are believed to further improve coronary artery imaging. Using dual-source CT scanners, pre-medication is not warranted in patients with a heart rate > 70 beats/min to obtain sufficient quality for coronary artery imaging (16, 17) with a negative predictive value of 98% and 100%, respectively. Whether pre-medication is warranted with single source 128-, 256- or 320-slice CT scanners is unknown since the experience with these new CT scanners is limited at the moment. In addition, it is also unknown whether these new CT scanners are able to detect diffuse non-significant CAD (luminal reduction <50%) with high accuracy.

In the present study, candidates for lung transplantation who will undergo conventional angiography as part of their screening work-up, are asked to participate in this study and to undergo CT coronary angiography as well. If the present study demonstrates that the negative predictive value of CT coronary angiography for the presence of CAD in lung transplantation candidates is as high as in patients with a clinical suspicion of cardiovascular disease, conventional angiography may only be indicated in a subgroup of lung transplantation candidates in whom CT coronary angiography reveals CAD.

#### Study objective

1. To assess the feasibility of performing CT coronary angiography in potential candidates for lung transplantation.

2. To assess the accuracy, especially the negative predictive value, of CT coronary angiography in the detection of both significant and diffuse non-significant CAD as compared to the gold standard conventional angiography in patients who are potential candidates for lung transplantation.

#### Study design

The study will start in the Erasmus MC as a pilot study first (Objective 1). Prospective, multi-centre (2 Dutch and 1 Belgian University Medical Centres), blinded cohort study in patients who are potential candidates for lung transplantation.

#### Study burden and risks

The individual patient will not benefit from participation into this study since the data from CT coronary angiography will be analyzed separately and only for research purposes. These data will not be provided to the treating physician.

So far, diagnostic invasive coronary angiography is used in order to assess the presence of CAD that may exclude patients from lung transplantation. Multi-detector CT coronary angiography has emerged as a non-invasive patient-friendly, inexpensive imaging modality that permits evaluation of both the coronary lumen and coronary vessel wall. If CT coronary angiography will achieve the same negative predictive values in potential lung transplantation candidates as has been described in other patient groups, diagnostic invasive coronary angiography may be reduced to only 20-25% of the patients who now undergo this examination as part of the routine work-up.

# 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**

Patients who are potential lung transplantation candidates and undergo conventional coronary angiography as part of their routine work-up.
Able to breath hold for 15 seconds.

- Willingness to give informed consent

# **Exclusion criteria**

- Arrhythmia (atrial fibrillation, refractory ventricular arrhythmia).

- Patients with high heart rates who have a contra-indication for beta-blockers and/or nitroglycerine and in whom alternative medication cannot be used in order to effectively perform CT -coronary angiography.

# Study design

# Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

#### Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	231
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	17-01-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

# **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 CCMO **ID** NL33616.078.10