

# Prognostic factors in chronic rejection after human lungtransplantation

Published: 05-09-2006

Last updated: 20-05-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35319

### Source

ToetsingOnline

### Brief title

BOS

### Condition

- Other condition
- Viral infectious disorders
- Bronchial disorders (excl neoplasms)

### Synonym

bronchiolitis obliterans syndrome, rejection

### Health condition

genetische pathogenese

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W, Roche Organ Transplantation Research Foundation

## Intervention

**Keyword:** Bronchiolitis Obliterans Syndrome, chronic rejection, lung transplantation

## Outcome measures

### Primary outcome

Prediction of BOS in patients after human lung transplantation in an early phase of the disease.

### Secondary outcome

Reactivity of T cells against target antigens as detected by the SEREX technique.

Relation of respiratory viruses and the development BOS.

Relation of respiratory viruses and the development of BOS.

Relation of genetic profile and the development of BOS.

Relation of proteins in condensated breath in patients after human lung transplantation and the development of BOS.

## Study description

### Background summary

Survival after lung transplantation is limited by the occurrence of obliterative bronchiolitis, which is characterised by the presence of bronchiolar inflammation and fibrosis in conjunction with progressive airflow obstruction. The pathogenesis is not well known but is associated with repeated injury to the graft by ischemia-reperfusion injury, rejection, infection and inflammatory reactions leading to damage of the airway epithelium followed by an exaggerated healing response. The development of Bronchiolitis Obliterans is usually characterized by a poor response to augmented immune suppression, but

may be effective in an early phase of the disease. In this study we will acquire insights in the multiple immunologic, biological, genetic and inflammatory effects on the transplanted lung in relation to the development of BOS.

### **Study objective**

The primary objective is acquiring insights in the development of BOS in patients after human lung transplantation in an early phase of the disease which can be used to improve immunotherapeutic handling in order to prevent or delay the onset of BOS.

### **Study design**

observational cohort study

### **Study burden and risks**

Because of the additional blood samples, a total of 24 x 40 ml in 4 years, there is a possibility of developing anemia. When this occurs and has therapeutic consequences the additional blood samples will temporarily be stopped.

## **Contacts**

### **Public**

Academisch Medisch Centrum

Heidelberglaan 100

Utrecht

NL

### **Scientific**

Academisch Medisch Centrum

Heidelberglaan 100

Utrecht

NL

## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients who undergo a lung transplantation

### Exclusion criteria

none

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 02-01-2007

Enrollment: 110

Type: Actual

## Ethics review

Approved WMO

Date: 05-09-2006

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 09-11-2010

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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

NL12752.041.06