# Cell subsets in blood as a biomarker for Bronchiolitis Obliterans Syndrome (BOS)

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**Ethical review** Approved WMO **Status** Will not start **Health condition type** Other condition

**Study type** Observational non invasive

## **Summary**

#### ID

**NL-OMON45481** 

#### Source

**ToetsingOnline** 

**Brief title** subsets BOS

### **Condition**

- Other condition
- Immune disorders NEC
- Respiratory disorders NEC

#### **Synonym**

"Bronchiolitis Obliterans Syndrome (BOS)" "Chronische afstoting na Longtransplantatie"

#### **Health condition**

Afstoting na long transplantatie

#### Research involving

Human

### **Sponsors and support**

**Primary sponsor:** Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

Keyword: Biomarker, Bronchiolitis Obliterans Syndrome, Lungtransplantation, Subsets

#### **Outcome measures**

#### **Primary outcome**

- 1. Difference in immune-cell subset composition in peripheral blood, between patients and controls
- 2. Activation marker expression
- 2. Cytokine production capacity
- 3. Differentiation directional

#### **Secondary outcome**

- 1. Sex
- 2. Age
- 3. Time between tranplantation and BOS diagnosis
- 4. Medication

## **Study description**

### **Background summary**

Lung transplantation is a last treatment option for patients with an end stage lung disease. Unfortunately, long-term survival after lung transplantation is severely limited by chronic lung allograft dysfunction, which usually manifests as bronchiolitis obliterans syndrome (BOS). About 50% of all lung transplantation patients dies within the first five years after transplantation. In addition, BOS reduces the quality of life and increases the cost of treatment. Clinically BOS manifests as an obstruction of the

airways and shortness of breath with a progressive and fatal course. The pathogenesis is driven by allo-immune and nonallo-immune mechanisms that can occur alone and simultaneously. Histologically it was shown that during BOS the allograft is inflitrated by leukocytes, followed by a process of injury, repair and extensive fibrosis where various leukocyte subsets are involved. This is the main reason why we are very interested in the dynamics and differentiation status of certain groups of leukocytes in the peripheral blood. Particulary monocytes surrounding the development of BOS. Infiltration and differentiation of certain fractions during inflammation and repair probably determines whether the immune response will lead to a pathological disorder.

#### Study objective

The objective of this study is to determine the composition and functional capacity of leukocyte fractions in the blood of lung transplantation patients. As a possible biomarker for BOS. It is expected that in patients with BOS the frequency and functional capacity of leukocyte fractions is changed in comparison with lung transplant patients without BOS.Phenotypical changes in blood, cytokine production capacity and differentiation potential of monocytes that are recruited during BOS are possible infomational en functional biomarkers. Therefore these leukocytes could also provide insight into the causal pathogenesis of BOS. Results from this research could be a valuable addition to the general understanding of BOS pathophysiology, and the role of monocytes in the process of inflammation and fibrosis.

### Study design

The proposed research is an observational study and is achievable within the timeframe of one year.

### Study burden and risks

Not applicable

Participants will not undergo any extra treatment or burden for this study. The blood is collected with informed consent, and the vena-puncture is already made for regular follow-up care.

### **Contacts**

#### **Public**

Sint Antonius Ziekenhuis

Koekoekslaan 1 Nieuwegein 3435CM NL

#### Scientific

Sint Antonius Ziekenhuis

Koekoekslaan 1 Nieuwegein 3435CM NL

### **Trial sites**

#### **Listed location countries**

**Netherlands** 

## **Eligibility criteria**

#### Age

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

#### Inclusion criteria

Patients that underwent a lung transplantation and are receiving follow-up care at the St. Antonius Hosptital. At this point in time there are 10 BOS diagnosed patients receiving follow-up care at the St. Antonius Hosptial. Next to these 10, we want to include 20 lung transplantation patients without BOS. 20 healthy controls will be acquired through corporations like Sanguin.

#### **Exclusion criteria**

- 1. Not willing to participate
- 2. Acute rejection after transplantation

## 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: Will not start

Enrollment: 30

Type: Anticipated

## **Ethics review**

Approved WMO

Date: 06-03-2017

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United

(Nieuwegein)

## 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 NL59424.100.16