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 differetiation 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

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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 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 Sanquin.

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