Exhaled breath analysis using eNose technology to detect acute cellular rejection and chronic lung allograft rejection in patients after lung transplantation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24102

Source
NTR

Brief title
SpiroNose study LTx

Health condition

Lung transplantation

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Erasmus MC Thorax Foundation

Intervention

Outcome measures

Primary outcome

Identification of different clusters of breathprints based on diagnosis (acute cellular rejection or chronic lung allograft dysfunction)

Secondary outcome

-

Study description

Background summary

In patients with end-stage lung disease, lung transplantation could be a lifesaving treatment option. However, patients after lung transplantation encounter higher health resource utilization, more transplant-related complications, and higher mortality rates compared to recipients of other solid organs. Early detection of complications such as acute cellular rejection (ACR) and chronic lung allograft dysfunction (CLAD) could prolong survival. Exhaled breath analysis using electronic nose (eNose) technology could provide a fast and non-invasive tool for the diagnosis of ACR and CLAD in patients after lung transplantation. In the Erasmus Medical Center we will ask lung transplant recipients to participate in this observational study.

The aim of this pilot study is to assess the feasibility and reliability of exhaled breath analysis using eNose technology for diagnosing ACR and/or CLAD in lung transplant recipients. To achieve this aim we will:

- Evaluate whether the breathprint of stable lung transplant recipients differ from lung transplant recipients with CLAD
- Evaluate whether the breathprint of stable lung transplant recipients differ from lung transplant recipients with ACR

Study objective

The eNose will be able to discriminate stable patients from patients with CLAD and ACR, and between ACR and CLAD

Study design

eNose measurements will be performed before or after routine outpatient clinic visits in stable patients and during each additional outpatient clinic visit

Intervention

Not applicable

Contacts

Public
Erasmus MC
Nynke Wijbenga

-
Scientific
Erasmus MC
Nynke Wijbenga

-

Eligibility criteria

Inclusion criteria

All outpatient lung transplant recipients of the Erasmus Medical Center

Exclusion criteria

Not applicable

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-07-2020
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion Date:	01-02-2021
Application type:	First submission

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
NTR-new	NL9251
Other	METC Erasmus MC : MEC-2019-0497

Study results

Summary results
N/A