Volatile organic compounds in exhaled breath for the detection of interstitial lung disease (VISION)

Published: 08-10-2020 Last updated: 09-04-2024

We hypothesize that exhaled breath analysis by eNose: is able to discriminate between patients with ILD, at risk for ILD (including post COVID-19 patients) and without ILD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON52688

Source ToetsingOnline

Brief title VISION

Condition

• Bronchial disorders (excl neoplasms)

Synonym lung fibrosis

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: eNose, interstitial lung disease (ILD), post-COVID fibrosis, volatile organic compounds

Outcome measures

Primary outcome

To determine the diagnostic accuracy of exhaled breath analysis by eNose at

point of care for discrimination between patients with ILD, at risk for ILD

(including post COVID-19 patients) and without ILD.

Secondary outcome

To assess the accuracy of exhaled breath analysis by eNose at baseline and

follow-up to identify diagnostic markers for early diagnosis and disease

progression of ILD.

Study description

Background summary

1.1 Interstitial lung disease

Interstitial lung disease (ILD) refers to a collective of respiratory diseases characterized by inflammation and fibrosis (scarring) of the pulmonary parenchyma. Among the known causes are systemic diseases, such as systemic sclerosis (SSc). Likewise, post COVID-19 may cause post-infectious damage to the pulmonary parenchyma leading to fibrosis. Patients with post-COVID-19 are by definition free of SARS-CoV2, the virus causing COVID-19. Fibrosis is an irreversible process and early detection of (SSc-)ILD is of pivotal importance. The golden standard for diagnosis is a chest high-resolution computed tomography (HRCT). However, this technique is considerably invasive as it requires a relatively high dose of radiation exposure in a particularly delicate area. [4, 5] Applying eNose technology during regular spirometry to obtain breath profiles may be a potent tool for non-invasive ILD detection.

1.2 Breath profiles from exhaled human breath

Exhaled breath contains volatile organic compounds (VOCs) that originate from both systemic and local metabolic processes, and which can be associated with normal physiology or pathophysiological inflammation or oxidative activity. In eNose technology, cross-reactive sensor arrays interact with the VOCs, resulting in a firing pattern. Probabilistic pattern recognition is applied to capture the full mixture of VOCs in exhaled air, corrected for ambient air, without identification of the individual components. [6-9] It has already been shown that eNose technology can be applied to distinguish lung cancer, inflammatory diseases and infectious diseases with accuracies comparable or even superior to traditional diagnostic tests [6, 11-15]. When clinically validated and accepted in daily practice, molecular profiling of exhaled air may provide a non-invasive, rapid point-of-care tool for the diagnosis and stratification of ILD.

The exhaled breath is real-time measured (< 1 minute) [10] by the eNose, and immediately transmitted to the online server BreathBase, where data is automatically may be analyzed and may online be shared between clinicians at multiple sites [16].

Study objective

We hypothesize that exhaled breath analysis by eNose: is able to discriminate between patients with ILD, at risk for ILD (including post COVID-19 patients) and without ILD.

Study design

This will be a prospective single-center case-control study in Leiden University Medical Center (LUMC). Patients who visit the outpatient clinic at the Department of Pulmonology are eligible for the study. Demographic data, medical history and routine clinical parameters of the individuals will be collected at baseline after obtaining informed consents. eNose measurements will be performed at baseline and at routine standard of care checkups.

Study burden and risks

Burden: extra measuring time of 1 minute, 10 minutes of data acquisition Risk: none.

Contacts

Public Academisch Medisch Centrum

Albinusdreef 2 Leiden 2333ZA

3 - Volatile organic compounds in exhaled breath for the detection of interstitial I ... 7-05-2025

NL Scientific Academisch Medisch Centrum

Albinusdreef 2 Leiden 2333ZA NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

Inclusion criteria

Eligible for participation in this study are all patients (>= 18 years of age): - with a known diagnosis of ILD (based on high resolution chest CT obtained in usual care)

- at risk for ILD (based on suspected diagnosis, chest X-ray, complaints or abnormal lung function obtained in usual care)

- without ILD (other diagnosis)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Recent (< 12 hours) intake of alcohol (checked by anamnesis of the study subject)

- Unwillingness or inability to comply with the study protocol for any other reason

In order to increase the applicability in clinical practice, there are no further restrictions.

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:	Recruitment stopped
Start date (anticipated):	04-11-2020
Enrollment:	180
Туре:	Actual

Ethics review

Approved WMO Date:	08-10-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	27-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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** NL74140.058.20