Forced oscillation technique: a novel method to monitor pulmonary fibrosis

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1. The aim of this study is to determine the minimal clinically relevant differences in impulse oscillometry2. To evaluate whether patients find the IOS measurements more comfortable compared to traditional methods.

Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON57392

Source
ToetsingOnline

Brief title
FLAIR2 study

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
interstitial lung disease, pulmonary fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: ZonMW,Maatschap Longziekten

Intervention

Keyword: interstitial lung disease, lung resistance, oscillometry

Outcome measures

Primary outcome

• Spirometrie parameter:

o Forced vital capacity (FVC)

o Forced expiratory volume in 1s (FEV1)

• Difusing capacity of carbondioxide (DLCO)

• Multiple FOT-parameters:

o Respiratory reactance (X5) --> retraction capacity + degree of peripheral obstruction

o Respiratory resistance (R5) --> total respiratory resistance (large airways + small airways + extrathoracic airways like the oropharynx and larynx)

o Respiratory resistance (R5) 20-15 Hz (Rrs20-5) --> small airways index

• RAND-36

• 5-point Likert-scale

Secondary outcome

Questionnaires

Patient Evaluation Form:

- VAS Cough: A visual analog scale (VAS) to assess the intensity of coughing experienced by the patient during the procedure.

- VAS Shortness of Breath: A VAS to measure the severity of breathlessness during the procedure.

- VAS Comfort: A VAS to evaluate the overall comfort level of the patient

during the test.

- General Procedure Feedback: Open-ended section for patients to provide feedback on the procedure, including any suggestions or issues encountered.

- Quality of life questionnaires (RAND-36 & L-PF)

Staff Evaluation Form:

Procedure Duration: Record the total time taken to complete the procedure.

Was it possible to perform the lung function and/or FOT measurement?

No: Provide a reason for the failure to complete the measurement:

- Coughing

- Shortness of breath

- Fatigue/Low energy

Yes:

- Assess the Quality of the Measurement: Rate on a scale: poor - moderate - adequate - good.

- Number of Attempts: Document how many attempts were required to obtain a usable measurement.

- Variation Between Measurements: Record any inconsistencies or variability across repeated measurements.

- Medical Conclusion Based on the Results: Provide a clinical interpretation of the results, considering the quality and reliability of the data obtained.

Study description

Background summary

The term interstitial lung diseases (ILDs) refers to a collective group of over one hundred distinct pulmonary conditions. All of these diseases involve the "interstitium," which is the space between the alveoli and blood vessels. Examples of ILDs include sarcoidosis, pulmonary fibrosis, alveolar proteinosis, and extrinsic allergic alveolitis.

This study primarily focuses on patients with pulmonary fibrosis. Pulmonary fibrosis is characterized by scarring of the lung tissue, leading to progressive shortness of breath, reduced lung function, and a poor prognosis. In idiopathic pulmonary fibrosis (IPF), the median survival is 2-3 years after diagnosis. At diagnosis, lung diffusion capacity is often reduced by 50%, and spirometry measurements typically indicate a restrictive pattern. Regular follow-up of lung function is crucial for assessing treatment efficacy, disease progression, and predicting the clinical course. IPF patients are generally monitored every 3-6 months with lung function tests. These tests require deep inhalations, which can provoke coughing episodes and be particularly challenging for patients already experiencing significant breathlessness.

Forced Oscillation Technique (FOT) may offer a suitable alternative lung function test for this patient population. FOT uses sound waves to measure the mechanical properties of the lungs during normal breathing. These sound waves are perceived as vibrations. By employing sound waves of different frequencies, IOS can assess resistance in both the large airways (high frequencies), as well as the small and peripheral airways (low frequencies). IOS is already used in other hospitals for pulmonary studies in children, intensive care patients, and in conditions such as COPD and asthma. Although there have been a limited number of studies on IOS measurements in pulmonary fibrosis patients, these studies suggest that IOS may offer advantages over traditional lung function tests. However, no long-term follow-up studies have yet demonstrated that IOS can effectively track disease progression over time. Therefore, this study aims to investigate whether IOS is suitable for monitoring disease progression and treatment effects in the long term.

Study objective

1. The aim of this study is to determine the minimal clinically relevant differences in impulse oscillometry
2. To evaluate whether patients find the IOS measurements more comfortable compared to traditional methods.

Study design

The study will be a prospective cohort study conducted at the ILD Centre of Excellence at St. Antonius Hospital in Nieuwegein. Participants will visit the

hospital as per their routine care schedule. Patients with pulmonary fibrosis who are scheduled for at least one lung function test or a high-resolution CT (HRCT) scan will be screened and approached for participation in this study. In addition to their standard tests, they will undergo an FOT (Forced Oscillation Technique) measurement. These measurements will be repeated during hospital visits to monitor disease progression. Patients enrolled in the study will be followed until the study's conclusion, for a maximum of 3 years.

Study burden and risks

The burden and risk of the research is considered negligible

Contacts

Public
Sint Antonius Ziekenhuis

koekoekslaan 1
Nieuwegeijn 3435 CM
NL
Scientific
Sint Antonius Ziekenhuis

koekoekslaan 1
Nieuwegeijn 3435 CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients with pulmonary fibrosis
aged 18 years and older

Exclusion criteria

pregnancy
breast feeding

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-02-2025
Enrollment:	125
Type:	Anticipated

Medical products/devices used

Generic name:	Airwave Oscillometry Device - Tremoflo
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-04-2025

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	NL88080.100.24