# Diagnosing expiratory flow limitation in COPD patietns with forced oscillation technique using linear regression in the time frequency domain

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The obtained FOT parameters can distinguish the group of COPD patients with expiratory flow limitation in body plethysmography from the patients without expiratory flow limitation in body plethysmography.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

# Summary

# ID

NL-OMON29991

**Source** ToetsingOnline

Brief title FOT and EFL

# Condition

Respiratory disorders NEC

**Synonym** Lung emfysema chronic bronchitis

**Research involving** Human

# **Sponsors and support**

#### Primary sponsor: Medisch Centrum Alkmaar

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#### Source(s) of monetary or material Support: Foreest Instituut Alkmaar

### Intervention

Keyword: COPD, Expiratory flow limitation, FOT, time-frequency analysis

### **Outcome measures**

#### **Primary outcome**

Xrs-8 (cmH20.s/L) (shorthand notation for the most negative value of Xrs during

expiration at 8 Hz)

Open or closed loop in pressure-volume loop measured by the body

plethysmography

#### Secondary outcome

Spirometry: FEV1 (L), FVC (L), IC (L), VC max (L),

CO-diffusion: TLCOSB, kCO

Body plethysmography: RV (L) TLC (L)

Forced oscillation technique:

Xrs-12,16,20,24 (cmH20.s/L)

Rrs-8,12,16,20,24 (cmH20.s/L)

Phase-8,12,16,20,24 (degrees)

Amplitude-8,12,16,20,24 (cmH20.s/L)

Other study parameters

Anthropometrical data

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# **Study description**

#### **Background summary**

The forced oscillation technique (FOT) is a non-invasive method to measure the mechanical properties of the respiratory system. Small amplitude pressure oscillations are applied to the mouth during apnea, but can also be superimposed on the normal breathing pattern. In COPD, expiratory flow limitation (EFL) is a major determinant of hyperinflation and exercise limitation. In this study we want to compare FOT using linear regression in the time frequency domain with the standard lungfuntion test for detecting expiratory flow limitation, the body plethysmography.

FOT has the advantage over body plethysmography that it can detect within-breath changes in flow limitation and follow the changes during multiple breaths.

We hypothesize that the obtained FOT parameters can distinguish the group with expiratory flow limitation in body plethysmography from the patients without expiratory flow limitation in body plethysmography. The goal for the future is to apply FOT in different lung function tests, especially during exercise testing, to be able to get more information on expiratory flow limitation during exercise in COPD patients.

### Study objective

The obtained FOT parameters can distinguish the group of COPD patients with expiratory flow limitation in body plethysmography from the patients without expiratory flow limitation in body plethysmography.

### Study design

Observational research without invasive measurements

#### Study burden and risks

Spirometry, body plethysmography and CO-diffusion are standard diagnostic tests performed in the pulmonary function test department. No extra risk are foreseen in this study. Salbutamol can give a tachycardia based on its pharmacological characteristics. Using salbutamol can give this adverse event which is seldom a serious adverse event.

Forced oscillation technique is not (yet) a standard diagnostic test. It is a non-invasive test. No adverse events are foreseen due to this test.

# 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**

All patients should meet the standard diagnostic criteria for COPD and they are current or exsmokers. The subjects must have stable disease at the time of the inclusion, which means that they cannot have an exacerbation of the COPD during the 4 weeks previous to the inclusion

### **Exclusion criteria**

History of exacerbation of COPD in the preceding month Upper airway obstruction Allergic Asthma OSAS

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Extreme obesity (BMI>35) Pulmonary disease other than COPD Clinically manifest cardiac disease (for example clinically relevant congestive heart failure, unstable angina pectoris)

# Study design

### Design

Observational non invasive
Other
Non-randomized controlled trial
Open (masking not used)
Active
Diagnostic

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	60
Type:	Anticipated

# **Ethics review**

Approved WMO Date: Application type: Review commission:

11-10-2006 First submission METC Noord-Holland (Alkmaar)

# **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** NL13873.094.06