Evaluation of diurnal variation in forced vital capacity in patients with fibrotic interstitial lung diseases using home spirometry

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The aim of this study is to evaluate the diurnal variation in pulmonary function in patients with fibrotic interstitial lung diseases, including IPF. Differences in morning and evening FVC will be assessed with twice daily home spirometry....

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

Summary

ID

NL-OMON46263

Source
ToetsingOnline

Brief title
Diurnal variation in FVC

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
fibrotic interstitial lung diseases, pulmonary fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fibrotic interstitial lung diseases, forced vital capacity, home monitoring, pulmonary function

Outcome measures

Primary outcome

The primary outcome is the difference in FVC between measurements in the

morning and afternoon

Secondary outcome

- Difference in Forced Expiratory Volume in 1 second (FEV1) between

measurements in the morning and afternoon.

- Difference in Peak Expiratory Flow (PEF) between measurements in the morning

and afternoon.

- Difference in HRQOL at baseline and after 6 weeks measured by K-BILD.

- Exploratory comparison of the differences in change in FVC between

different fibrotic interstitial lung diseases.

- Difference in activity (steps) between morning and afternoon

Study description

Background summary

Fibrotic interstitial lung diseases (ILDs) are a group of lung diseases affecting the interstitium of the lung. One of the most common ILDs is idiopathic pulmonary fibrosis (IPF).IPF is a chronic progressive disease with often a poor quality of life and a declining lung function. Recently two anti-fibrotic drugs became available that slow down the decline of lung function, measured with the forced vital capacity (FVC) as most important outcome measure. Unfortunately, FVC measurements have an inherent variability and disease course is often unpredictable. The standard practice of FVC measurement once per three months is not enough to reliably assess changes in disease course in the individual patient.

Furthermore, from a clinical trial perspective, more refined techniques are needed to measure FVC. In IPF, new drugs are being investigated on top of *standard care* with anti-fibrotic medication, likely resulting in smaller margins of change and need for lengthy trials and large numbers of patients, which are not only very expensive but also hardly feasible in a rare disease as IPF.

We performed a pilot study using home spirometry in this patient group in the Erasmus MC. Four patients performed home spirometry twice daily (morning and afternoon) on their own initiative. Surprisingly, all patients had a higher FVC in the morning compared to the afternoon. However, these are preliminary results in a small group of patients, which should be evaluated in a larger observational study to assess whether the diurnal variations we deteceted are realistic and clinically relevant. If so, this will have consequences for future clinical trials and daily practice. Further appointments for pulmonary function should be planned on approximately the same time if there is indeed a diurnal variation in FVC. Furthermore, more insights are needed to assess differences in the change in pulmonary function between fibrotic interstitial lung diseases.

Study objective

The aim of this study is to evaluate the diurnal variation in pulmonary function in patients with fibrotic interstitial lung diseases, including IPF. Differences in morning and evening FVC will be assessed with twice daily home spirometry. Furthermore, we aim to assess difference in change in FVC over a 12 week period between different fibrotic interstitial lung diseases.

Study design

This is a prospective, single-centre, non-randomized observational study in the Erasmus Medical Center, Rotterdam.

Study burden and risks

There will be no risks associated with this study and the burden is small. Patients will be asked to perform twice daily spirometry for the first six weeks, once daily spirometry for the last six weeks, wear an activity tracker, fill in weekly symptom scores, and complete the K-BILD questionnaire at baseline, after six weeks and after 12 weeks. Participants may directly benefit from this study, because they can have more insights in there disease course by keeping track of their pulmonary function.

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 diagnosed with fibrotic interstitial lung disease

Exclusion criteria

- Not able to speak, read or write in Dutch
- Not able to comply to the study protocol, according to the judgement of the investigator and/or patient
- Life expectancy less than six months, according to the judgment of the investigator.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23961
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66799.078.18
OMON	NL-OMON23961