Dagelijkse variatie in longfunctie bij patiënten met longfibrose

No registrations found.

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

Summary

ID

NL-OMON23961

Source
NTR

Brief title
DIVA study

Health condition

fibrotic interstitial lung disease , idiopathic pulmonary fibrosis, pulmonary function, eHealth

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam
Source(s) of monetary or material Support: Boehringer-Ingelheim

Intervention

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, 6 weeks and after 12 weeks measured by K-BILD.

- Absolute change from baseline to twelve weeks in FVC measured by home-spirometry

- Absolute change from baseline to twelve weeks in FVC measured by hospital spirometry

- Difference in hourly activity in the hour before morning spirometry and afternoon spirometry

- Exploratory comparison of the differences in change in FVC between different fibrotic ILDs.

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 disease with progressive fibrosis of the lung tissue, resulting in a poor prognosis and a devastating impact on the lives of patients.

Forced Vital Capacity (FVC) is used as the routine physiological measure to follow up patients with ILD and is widely accepted as the best assessment of progression of fibrosis. Unfortunately, FVC measurements have an inherent variability and disease course is often unpredictable. The standard practice of FVC measurements once per three months is not enough to reliably assess changes in disease course in the individual patient, guide

treatment decisions and timely detect acute exacerbations. Furthermore, from a clinical trial perspective, more refined techniques are needed to measure FVC. The use of information communication technology in health care, also named eHealth, is a promising solution to improve the quality of care. EHealth allows remote exchange of data between patients and healthcare professionals which enables monitoring, research and management of long term conditions. This creates an opportunity for earlier intervention by healthcare professionals, which may prevent a hospital admission.

We have developed a home monitoring program for patients with pulmonary fibrosis, integrating daily home spirometry and online patient-reported outcomes. The bluetooth-enabled spirometer transmits data real-time via a secure encrypted connection, enabling patients and healthcare providers to access data directly. In the first pilot study with this system there appeared to be a diurnal variation in FVC. However, these were preliminary results in a small group of patients. A larger observational study is required to assess whether the diurnal variations we detected in our pilot study are realistic and clinically relevant.

Study objective

Forced Vital Capacity (FVC) is used as the routine physiological measure to follow up patients with fibrotic interstitial lung diseases (ILD). The standard practice of FVC measurement once per three months is not enough to reliably assess changes in disease course in the individual patient, guide treatment decisions and timely detect acute exacerbations. In our previous pilot study using home spirometry in patients with idiopathic pulmonary fibrosis (IPF), we found that there appeared to be a diurnal variation in FVC in some of the participants.

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.

Study design

Baseline, week 6, week 12, weekly VAS scores, daily spirometry

Intervention

This is a prospective, single-centre, non-randomized observational study. All consecutive patients with fibrotic interstitial lung diseases, with a scheduled visit to the outpatient clinic of the pulmonary department in the Erasmus MC Rotterdam, will be informed by the lung physician about the study. All patients willing to participate will have to sign informed consent first. Patients will be included during this regular outpatient clinic visit. Participants will be asked to perform twice daily spirometry during six weeks, and subsequently six weeks once daily spirometry, using a handheld spirometer in combination with an application on a

tablet. Furthermore, patients will be asked to wear an activity tracker which records steps per day and steps per hour. No extra hospital visits will take place during the study. Patients will complete the Kings Brief Interstititial Lung Disease Questionniare (K-BILD) online to evaluate health-related quality of life (HRQOL) at baseline, after 6 weeks and end of the study . Furthermore, patients will report their symptoms (cough, dyspnea, fatigue, general complaints) on visual analogue scales (VAS) weekly online.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Diagnosis of fibrotic interstitial lung disease discussed in a multidisciplinary team meeting

Exclusion criteria

- Not able to speak, read or write in Dutch

- Not able to comply to the study protocol, according to the judgment of the investigator and/or patient

- Life expectancy less than six months, according to the judgment of the investigaor

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):	20-11-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-12-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46263
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7416
NTR-old	NTR7649
CCMO	NL66799.078.18
OMON	NL-OMON46263

Study results

Summary results
n/a