Dagelijkse variatie in longfunctie bij patiënten met longfibrose

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23961

Bron
NTR

Verkorte titel
DIVA study

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam
Overige ondersteuning: Boehringer-Ingelheim

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the difference in FVC between measurements in the morning and afternoon.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-11-2018
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46263
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
n/a