A multi-center, real-world exploratory cohort study to evaluate cough frequency, severity, and impact on quality of life in patients with non-idiopathic pulmonary fibrosis interstitial lung disease

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

Summary

ID

NL-OMON51461

Source
ToetsingOnline

Brief title
Evaluating cough and impact on quality of life in pulmonary fibrosis

Condition

- Respiratory disorders NEC

Synonym
interstitial Lung disease, Pulmonary fibrosis

Research involving

Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Bedrijf: Boehringer Ingelheim

Intervention

Keyword: Pulmonary Fibrosis Evaluate Impact

Outcome measures

Primary outcome

Exposures

Not applicable.

Outcomes

The primary outcomes of the study are the frequency of cough and the distribution of coughing fits during daytime and nighttime, in a population of subjects with non-IPF fibrosing ILDs using the first analyzable 24 hours cough recording through the VitaloJAK monitoring.

The secondary outcomes of this study are: 1) variability of cough for all subjects based on two VitaloJAK recordings, 2) patient-reported impact of cough symptoms on quality of life using LCQ; 3) patient-reported cough severity, urgency, and shortness of breath using VAS; 4) patient reported impression of severity, frequency, and impact of cough using PGI index for cough symptoms reported daily over the entire study period, i.e. a period of maximum 4 weeks; 5) patient-reported overall change in cough symptoms since the beginning of the

study using PGIC; 6) patient-reported overall impact of cough on quality of life using item 18 of the L-PF Impacts Questionnaire; 7) health utilities using EQ-5D-5L; and 8) measurements of physiological parameters including FVC and DLCO.

Exploratory outcomes of this study are the analysis of blood and exhaled breath biomarkers.

Covariates

The following covariates, where available, will be collected and assessed at study enrollment: 1) subject demographics; 2) current pregnancy status; 3) time since diagnosis of non-IPF fibrosing ILD and type of non-IPF fibrosing ILD; 4) non-IPF fibrosing ILD-related medication and all concomitant medications, based on medical prescription history, in the 6 months prior to study entry and during the study period; 5) comorbidities; 6) most recent chest High-Resolution Computed Tomography (HRCT)pattern; 7) smoking status/history, number of cigarettes per day, and number of smoking years; and 8) history of COVID-19 infection and symptoms, and vaccination against COVID-19.

Secondary outcome

N/A

Study description

Background summary

Epidemiological data and understanding of progressive fibrosing interstitial lung disease (PF-ILD) aside from the most common and the most severe idiopathic pulmonary fibrosis (IPF), is very limited to date. Similar to patients with IPF, patients with fibrosing interstitial lung diseases other than IPF (non-IPF fibrosing ILDs), experience and report persistent cough as a common symptom. Cough has been shown to be an independent predictor of disease progression in patients with IPF, and it has been hypothesized that cough may enhance fibrotic remodeling via cough induced mechanical stress. Therefore, a better understanding of cough frequency and severity across patients with pulmonary fibrosis and different underlying diagnoses, and its relation to functional or imaging parameters, is important to elucidate its potential association with disease progression in the future. Nevertheless, the incidence of persistent and disruptive cough in the population of non-IPF fibrosing ILD patients, as well as cough pattern and frequency, and the impact of cough on quality of life, are not well-described.
Therefore, the aim of this study is to assess the frequency, patient-reported severity and impact of cough on quality of life, and the distribution of coughing fits during the daytime and nighttime, in a patient population with non-IPF fibrosing ILDs, to expand the understanding of the disease and its symptoms, thereby narrowing the existing gap in knowledge.

Study objective

The overall aim of this study is to assess the frequency, patient-reported severity and impact of cough, and the distribution of coughing fits during the daytime and nighttime, in a population of patients with non-IPF ILDs.

Primary objective:
The primary objective of this study is to objectively evaluate the frequency of cough, and the distribution of coughing fits during daytime and nighttime, in a population of subjects with non-IPF fibrosing ILDs using the first analyzable 24 hours cough recording through the VitaloJAK monitoring.

Secondary objectives:
The secondary objectives for this study are threefold:
1. To assess the daytime, nighttime, and 24 hours variability of cough between the two sets of 24 hours cough recordings performed at an interval of at least 14 days
2. To estimate the severity and impact of cough symptoms on subject*s quality of life using Leicester Cough Questionnaire (LCQ), visual analogue scales (VAS) for cough (severity, urgency, shortness of breath), 3-item Patient Global Impression (PGI) of Cough Symptoms assessment, Patient Global Impression of Change (PGIC) assessment, item 18 of the Living with Pulmonary Fibrosis (L-PF) Impacts Questionnaire, and EuroQol five dimensions five levels (EQ-5D-5L)
3. To analyze possible correlations between objective cough measurements, patient-reported outcomes (PROs), and physiological parameters including forced vital capacity (FVC) and diffusing capacity of the lungs for carbon monoxide

(DLCO)

Exploratory objective:
The exploratory objective of this study is to analyze possible correlations between objective cough measurements, and blood and exhaled breath biomarkers.

Study design

A multi-center, real-world exploratory cohort study based on newly collected data of approximately 100 evaluable subjects with non-IPF fibrosing ILDs from various sites in the North America and Europe.

Study burden and risks

N/A

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

- Provision of signed informed consent in writing prior to study data collection
- Subject aged 18 years or over
- Subject diagnosed with non-IPF fibrosing ILD

Exclusion criteria

- Cough due to etiology other than ILD (e.g., allergic rhinitis, Gastroesophageal Reflux Disease (GERD))
- Other respiratory disorders including, but not limited to, a current diagnosis of any obstructive disease including chronic obstructive pulmonary disease (COPD) and asthma, active tuberculosis, lung cancer in treatment or in medical history, sleep apnea, known alpha-1 antitrypsin deficiency, cor pulmonale, clinically significant pulmonary hypertension, clinically significant bronchiectasis, or other active pulmonary diseases
- Respiratory infection or use of antibiotics for respiratory cause within 4 weeks prior to study entry
- Initiation or change in dose or type of anti-tussive medication, angiotensin-converting enzyme (ACE) inhibitors, or corticosteroids in the 4 weeks prior to study entry
- Subject with airflow obstruction (forced expiratory volume in one second (FEV1)/FVC<0.7) or known significant spirometry response to bronchodilator

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed

Start date (anticipated):	02-05-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	SpiroNose
Registration:	No

Ethics review

Approved WMO Date:	11-04-2022
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL79595.099.22

Study results

Date completed:	31-03-2023

Results posted: 15-02-2024

First publication
18-01-2024