Observational study of the effect of Pirfenidone on cough in patients with idiopathic pulmonary fibrosis.

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In this study we want to objectively measure the effect of Pirfenidone on cough in patients with IPF.

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-OMON41593

Source
ToetsingOnline

Brief title
Cough-IPF

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Idiopathic pulmonary fibrosis, scarring of the lung

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Intermune International AG

Intervention

Keyword: cough, idiopatic pulmonary fibrosis, quality of life

Outcome measures

Primary outcome

To measure with a validated cough recorder the effect of Pirfenidone on cough frequency in patients with IPF

Secondary outcome

• To measure the effect of Pirfenidone on health status and cough severity using the Leicester Cough Questionnaire and Visual Analogue Score.

• To assess the impact of cough on quality of life, anxiety and depression (baseline, week 4 and 12)

• To assess the change in cough frequency measured by cough recorder at 4 weeks compared to baseline

• To correlate change in cough frequency in relation to lung function

• To identify clinical characteristics predictive of cough response

Study description

Background summary

Idiopathic Pulmonary Fibrosis (IPF) is a progressive fibrotic lung disease of unknown cause with a median survival of 3-5 years. No curative treatment exists, though in 2011 Pirfenidone was approved for the treatment of IPF as it appeared to slow down the decline in lung function. In patients with IPF, the most common symptoms are cough and breathlessness. Cough is not only a major distressing and disabling symptom but also an independent predictor of disease progression and death in IPF. Recent preliminary data suggest a possible effect of Pirfenidone on cough.

Study objective

In this study we want to objectively measure the effect of Pirfenidone on cough in patients with IPF.

Study design

This is a prospective, observational, international multicenter study.

Study burden and risks

Patients with IPF participating in this study will not have personal benefit from participating in this study. The burden is low, patients will be asked to carry a small ambulatory cough monitor for three times 24 hours and to fill in questionnaires three times at there regular outpatient visits (duration 3 X 30 minutes).There is no risk in participation of the study. Recording cough sounds and filling in questionnaires is not expected to change the course of their disease or cause side effects. Treatment decisions will be at the discretion of the treating physician and not be influenced by the study. The outcome of the study may improve future care of patients with IPF.

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

- Diagnosis of IPF according to ATS/ERS criteria (5), definite and probable patients will be eligible
- Written informed consent
- Daily cough related to IPF (exclusion of other causes) present > 8 weeks
- TLCOc >= 30% and FVC >= 50%
If a patient is not able to perform a reliable TLCOc measurement because of for instance coughing; TLCOc should be >= 30 % within the past 6 months and FVC should be >= 50% and no emphysema present on CT and no severe pulmonary hypertension on echo.
- Pirfenidone therapy about to be initiated
- if a history positive for Gastro Esophageal Reflux (GER), using proton pump inhibitor (PPI) > 4 weeks

Exclusion criteria

Opiates, antitussive medication, antihistamines, steroids > equivalent of 10 mg prednisone or NAC within two weeks before study
- Change of steroid < 10 mg, inhalation steroids within 2 weeks of the study
- History of bronchial hyper responsiveness or asthma or relevant airway obstruction (FEV1/FVC < 0.7)
- within 6 weeks of the start signs of respiratory tract infection, change of sputum production and fever.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2013
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-10-2014
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL44729.078.13