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Observational study of cough severity in patients with idiopathic pulmonary fibrosis cough

Submission date
26/04/2021

Recruitment status
No longer recruiting

Registration date
27/04/2021

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate a new patient questionnaire that measures the severity of cough in patients with idiopathic pulmonary fibrosis (IPF). Cough is a common symptom in patients with IPF and is frequently cited as one of the most burdensome aspects of this terminal disease. NeRRe Therapeutics (which is funding the research) is developing a potential treatment for chronic cough in IPF and plans to use this cough questionnaire in clinical trials to see whether the treatment is effective. However, before the questionnaire can be used in trials testing this potential treatment, information needs to be gathered on the questionnaire itself.

Who can participate?
Patients aged 40 and over who have a troublesome cough due to IPF

What does the study involve?
Participants will be asked to complete a cough diary containing this questionnaire every evening for two separate 1-week periods with a 1-week gap between these two periods. The cough diary will be completed using an app on a phone or tablet. The cough diary app has been designed to be very simple to use and should take no more than a minute each day. At the end of the diary completion period, participants will be invited to have a telephone interview with a trained researcher to find out more about their cough and to gather feedback on the cough diary. This interview will be optional, and participants will still be able to participate in the study even if they do not wish to have an interview.

What are the possible benefits and risks of participating?
There will be no direct benefit to participants. However, the results may help the development of future treatments for chronic cough due to IPF.

Where is the study run from?
NeRRe Therapeutics (UK)

When is the study starting and how long is it expected to run for?
December 2020 to July 2021

Who is funding the study?
NeRRe Therapeutics (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
293624

Protocol serial number
IPF-Obs-01

Study information

Scientific Title
An observational study to record cough symptom severity in patients with chronic cough due to idiopathic pulmonary fibrosis

Study objectives
The objective of this observational study is to evaluate a new patient questionnaire that measures the severity of cough in patients with idiopathic pulmonary fibrosis (IPF).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2021, West of Scotland REC 3 (Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0211; WoSREC3@ggc.scot.nhs.uk), REC ref: 21/WS/0014

Study design
Multi-centre observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Chronic cough due to idiopathic pulmonary fibrosis

Interventions
Participants will be asked to record measures of coughing severity in a diary app once a day for two separate 7 day periods with approximately 1 week between the two periods. On the first day of diary completion, participants will complete two assessments: the Cough Severity numerical rating scale (NRS) and the cough severity visual analogue scale (VAS). On the seventh day of diary completion, participants will complete two assessments: the Cough Severity NRS and the global rating of severity (GRS). On the last day of diary completion, participants will complete all three assessments: the Cough Severity NRS, the cough severity VAS and the GRS. On all other diary completion days, participants will just complete the Cough Severity NRS.

Intervention Type
Other

Primary outcome(s)
Cough severity on a 0-10 scale (where 0 is “no coughing” and 10 is “coughing as bad as you can imagine”) using the cough severity numerical rating scale (NRS) on Days 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14

Key secondary outcome(s))
1. Cough severity (none, mild, moderate or severe) measured using the Global Rating Scale (GRS) on Days 7 and 14

2. Cough severity (between 0 and 100 mm, where 0 is “no coughing” and 10 is “coughing as bad as you can imagine”), measured using the cough severity visual analogue scale (VAS) on Days 1 and 14
3. Patients’ experience of chronic cough due to IPF collected by interview between Day 14 and 42

Completion date
22/07/2021

Eligibility

Key inclusion criteria
1. Male or female, aged ≥40 years of age
2. Able to understand and comply with the requirements of the study and sign Informed consent forms
3. Good understanding of written and spoken English
4. Diagnosis of IPF established according to the 2018 joint ATS/ERS/JRS/ALAT Clinical Practice Guideline
5. Life expectancy of at least 6 months
6. Cough that is attributed to IPF and which has been present for at least 8 weeks
7. Cough severity rated at least 4 on the Cough Severity NRS at screening (verbal assessment acceptable for screening)
8. If taking pirfenidone or nintedanib, the dose should have been stable for at least 1 month prior to screening

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Recent respiratory tract infection (<4 weeks prior to Screening)
2. Recent acute exacerbation of IPF (<8 weeks prior to Screening)
3. Current smokers or ex-smokers with <6 months’ abstinence prior to Screening
4. Any clinically significant or unstable medical or psychiatric condition that would, in the opinion of the investigator, interfere with the subject's ability to participate in the study safely
5. Participation in any clinical research study evaluating an investigational drug or therapy within 30 days or within 5 half-lives (whichever is longer) of the investigational drug prior to Screening.

If the subject was in an observational clinical study no washout is required
6. Subjects who, in the opinion of the Investigator, should not participate in the study for any other reason

Date of first enrolment
08/04/2021

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's Hospital
Guys and St Thomas NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Tussogenics Ltd
11 Beck Lane
Broughton
United Kingdom
DN20 0HR

Sponsor information

Organisation
NeRRe Therapeutics (United Kingdom)

ROR
https://ror.org/04kyz2p97

Funder(s)

Funder type
Industry

Funder Name
NeRRe Therapeutics (United Kingdom)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from info@nerretherapeutics.com to academic researchers who have a bona fide reason to request them. Only aggregated data will be provided as participants did not give consent for subject level data to be provided to parties other than NeRRe. Requests for data should include a summary of the research project including its objectives, the funding source, the role of the study data in achieving these objectives, the proposed analysis methods and publication plans.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		17/08/2022	17/08/2022	No	No
HRA research summary			28/06/2023	No	No