

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

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| Submission date 26/04/2021 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 27/04/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 17/08/2022 | Condition category Respiratory | <input type="checkbox"/> 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?
Susan Seymore
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293624

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IPF-Obs-01, IRAS 293624

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

Secondary study design

Longitudinal study

Study setting(s)

Home

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

29/12/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

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

England

United Kingdom

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)

Sponsor details

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Sponsor type

Industry

Website

<http://nerretherapeutics.com/>

ROR

<https://ror.org/04kyz2p97>

Funder(s)

Funder type

Industry

Funder Name

NeRRe Therapeutics (United Kingdom)

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

31/07/2023

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 |