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Study to investigate longitudinal changes in breath biomarkers in idiopathic pulmonary fibrosis

Submission date
26/07/2018

Recruitment status
No longer recruiting

Registration date
17/09/2018

Overall study status
Completed

Last Edited
15/08/2019

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Idiopathic pulmonary fibrosis (IPF) is a chronic lung condition associated with poor prognosis and an average life expectancy worse than most cancers. Effective treatment which slows the progression of IPF has recently become available but it is costly and at present is limited to patients who meet specific criteria based on their breathing tests. The breathing tests currently available to monitor progression of the disease are not always reliable and do not predict which patients will respond to treatment. The aim of this study is to use a technique which analyses breath samples to provide a profile of the chemicals which are present in the exhaled breath of patients with IPF. The researchers want to know whether this breath profile differs between patients with IPF depending on the severity of their disease. They also want to know whether the breath profile changes over time and whether this can be used to predict which patients are likely to have rapid progression of their disease. It is hoped that this will provide an accurate way of monitoring the disease and predicting progression. They also plan to look at the breath profile of patients receiving specific disease modifying treatment for IPF to see whether breath analysis can predict which patients will respond to treatment.

Who can participate?
Patients aged 18 and over with IPF

What does the study involve?
Participants attend 4 visits at 3 month intervals to provide breath samples, blood samples and complete a questionnaire. Breath is collected using a device called the ReCIVA (Owlstone Medical, Cambridge, UK). This is a mask which holds four steel tubes containing material which collects breath. Participants breathe into the mask for about 8 minutes. The tubes are transported to a laboratory where the breath samples are analysed.

What are the possible benefits and risks of participating?
The study will not provide specific individual benefit to the participants involved but will help to progress the understanding of IPF and could help to improve management of the condition in the long term. There are no specific risks associated with breath sampling. Sampling requires the

use of a face mask which some patients may find uncomfortable, and in the unlikely event that this is the case they will be permitted to stop sampling immediately.

Where is the study run from?
1. Wythenshawe Hospital, Manchester University NHS Foundation Trust (UK)
2. Norfolk and Norwich University Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2017 to July 2020

Who is funding the study?
Boehringer Ingelheim (Germany)

Who is the main contact?
Dr Conal Hayton

Study website
www.ipfvoc.org

Contact information

Type(s)
Public

Contact name
Dr Conal Hayton

ORCID ID
http://orcid.org/0000-0001-8907-0643

Contact details
North West Lung Centre
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Manchester
United Kingdom
M23 9LT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BI 1199-0311

Study information

Scientific Title
A pilot study to investigate longitudinal changes in breath biomarkers in idiopathic pulmonary fibrosis

Acronym
IPF VOC

Study objectives
Patients with idiopathic pulmonary fibrosis have different breath profiles based on the severity of their disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 6, 27/11/2017, IRAS Project ID: 227743, HRA approval 10/05 /2018

Study design
Observational longitudinal cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Available at www.ipfvoc.org

Health condition(s) or problem(s) studied
Idiopathic pulmonary fibrosis

Interventions
This is an observational study involving the collection of clinical data, 2 breathlessness questionnaires and exhaled breath samples. Breath will be collected using a device called the ReCIVA (Owlstone Medical, Cambridge, UK). This is a mask which holds 4 steel tubes containing absorbent material which collect breath. Participants will breathe into the mask for approximately 8 minutes. The tubes will be transported to a laboratory where the breath samples will be analysed using a mass spectrometer to identify volatile organic compounds (VOCs). Breath samples will be taken on each of the visits (maximum of 5 samples). There is also an option to provide serum samples on each visit, which will be stored for later use.

Intervention Type
Other

Primary outcome measure
Volatile Organic Compounds, measured using mass spectrometry, that can distinguish between IPF patients based on their baseline GAP stage (I, II or III)

Secondary outcome measures
1. Volatile Organic Compounds, measured using mass spectrometry, that can distinguish between patients based on change in FVC after 12 months [defined as non-decliners (relative FVC decline <5%), slow decliners (relative FVC decline 5-10%), fast decliners (relative FVC decline >10%)]
2. Volatile Organic Compounds, measured using mass spectrometry, which can distinguish between patients with an increase in MRC dyspnoea score of 1 or more after 12 months and those without a change
3. Volatile Organic Compounds, measured using mass spectrometry, that can distinguish between patients with an increase in USCD SOBQ scores of 5 or more after 12 months compared to those without a change
4. Volatile Organic Compounds, measured using mass spectrometry, that can distinguish between patients that respond to antifibrotic treatments and those that do not (response defined as less than 10% in relative FVC decline at 12 months)
5. Volatile Organic Compounds, measured using mass spectrometry, that can distinguish between patients having an exacerbation of IPF and those who are not

Overall study start date
01/02/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Age ≥ 18
2. Multi-disciplinary team diagnosis of idiopathic pulmonary fibrosis as per international consensus guidelines

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

80

Total final enrolment
88

Key exclusion criteria
1. Significant respiratory co-morbidity (i.e. where the major respiratory diagnosis is not IPF)
2. FEV1/FVC ratio < 70% on full lung function testing
3. Residual volume ≥ 90 % predicted on full lung function testing
4. Current smoker
5. Received treatment for acute lower respiratory tract infection with last 4 weeks
6. Unwilling to participate in the study

Date of first enrolment
09/07/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital, Manchester University NHS Foundation Trust
Southmoor Road,
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Norfolk and Norwich University Hospital NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Manchester University NHS Foundation Trust

Sponsor details
Wythenshawe Hospital
Southmoor Road
Wythenshawe
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England
United Kingdom
M23 9LT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
Boehringer Ingelheim

Alternative Name(s)
Boehringer Ingelheim International GmbH

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Protocol will be made available via www.ipfvoc.org. The trialists aim to publish this study in a peer-reviewed scientific journal.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Conal Hayton. Type of data – all data anonymised, demographic, clinical and VOC data. Data will become available once all primary analysis completed (expected to be 6 months after last participant completes study). Data will be available for 12 months. Data will be available for non-commercial research.

IPD sharing plan summary

Available on request