Characterising Patient Pathways to the Diagnosis of Idiopathic Pulmonary Fibrosis: Real World Data Study

First published: 19/09/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS20994

Study ID

30193

DARWIN EU® study

No

Study countries

United Kingdom

Study description

An exploratory historical UK database study characterising patient pathways to diagnosis of IPF, identifying and quantifying blocks and red flags through primary, secondary, and tertiary care settings.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 20/08/2026

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/06/2017

Actual: 28/06/2017

Study start date

Planned: 01/06/2018

Actual: 07/07/2018

Date of final study report

Planned: 31/08/2018

Actual: 28/08/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

OPRI-R1704_Protocol_Characterising patient pathways to IPF diagnosis_Protocol_V2.1.pdf (824.55 KB)

OPRI-R1704_Protocol_Characterising patient pathways to IPF diagnosis_Protocol_V2.3 clean.pdf (465.42 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To explore the real life clinical pathways and feasibility of characterising pathways towards diagnosis of idiopathic pulmonary fibrosis (IPF) using real-world data.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Short description of the study population

Patients with an Idiopathic Pulmonary Fibrosis (IPF) diagnosis code.

All patients must fulfil the following inclusion criteria:

1. A diagnostic Read code for IPF (specific or broad definition) on or before 1st May 2017
2. ≥1 year of continuous data prior to the index date
3. Age ≥30 years at index date

4. Determined to be highly likely to have an IPF diagnosis based on database rules developed from the pilot qualitative study

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Idiopathic Pulmonary Fibrosis (IPF) patients

Estimated number of subjects

2223

Study design details

Outcomes

Patient pathways to IPF diagnosis will be characterised from the period starting at the first symptoms and clinical features suggestive of IPF up to IPF diagnosis date using pathway features. Pathway features will be defined and standardised after an exploratory, qualitative review of a subgroup of patients, followed by a quantitative summary of pathways for IPF diagnoses. The different pathways characterised will be compared to the ideal pathway that highlights the blocks and red flags to reduce the time to IPF diagnosis in existing and potential IPF

patients. Blocks will be identified and quantified as delays (additional time spent) in the pathway due to the blocks. Red flags are features, signs and symptoms in a patient that indicate development of IPF.

Data analysis plan

Data will be analysed in two stages:1) An exploratory, qualitative review in a subset of the full study population using: a. Read codes and free text in medical records by primary care clinicians recorded in OPCRD, andb. Secondary and tertiary care referral data, including anonymised, scanned clinic letters from specialists and free text, from OPC's review of in-practice data 2) A quantitative, descriptive summary of the full study population using Read codes and free text in OPCRD only.For the qualitative review, a database algorithm will be developed by compiling code lists for read codes and words list associated with identification of first symptoms and clinical features suggestive of IPF. For the quantitative summary, data will be extracted for variables defined by the code and word lists. For continuous variables, mean, SD, median, inter-quartile range, minimum and maximum will be reported. For categorical variables, frequencies and percentages will be reported.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No