Characteristics of IPF patients initiating nintedanib, pirfenidone or no antifibrotic treatment in the US

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Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS30039

Study ID

30365

DARWIN EU® study

No

Study countries

☐ United States

Study description

This retrospective database study aims to understand characteristics of Idiopathic Pulmonary Fibrosis (IPF) patients treated with nintedanib and pirfenidone, as well as patients who do not receive a prescription for an antifibrotic treatment. The primary objective is to describe and compare demographic, clinical, and other characteristics of IPF patients initiating nintedanib, pirfenidone, or not receiving prescription antifibrotic treatment. The secondary objective is to compare and contrast the probability of receiving nintedanib vs. pirfenidone and nintedanib or pirfenidone vs. untreated in IPF patients using baseline patient characteristics.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Chakkarin Burudpakdee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/09/2018

Actual: 14/09/2018

Study start date

Planned: 04/12/2018

Actual: 04/12/2018

Date of final study report

Planned: 06/06/2019

Actual: 06/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

IQVIA BI IPF channeling AP_12182018_v2.pdf (683.77 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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To understand characteristics of IPF patients treated with nintedanib and pirfenidone, as well as patients who do not receive a prescription for an antifibrotic treatment in the United States

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

US population receiving healthcare in the ambulatory setting.
Patients were included in one of three study cohorts based on prescription history from October 1, 2014 to April 30, 2018, allowing for a 12-month pre-index period to describe patient demographic, clinical and treatment characteristics.

Age groups

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

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

13300

Study design details

Outcomes

The primary outcome will be the ASD and p-value comparing baseline patient characteristics between patients treated with nintedanib vs. pirfenidone, nintedanib vs. untreated and pirfenidone vs. untreated, The secondary outcomes are the adjusted odds ratios of receiving one treatment over another (or probability of receiving antifibrotic treatment) between the following cohorts:• Nintedanib vs. pirfenidone• Treated patients (i.e. nintedanib or pirfenidone) vs. untreated

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Data analysis plan

For the primary objective, baseline patient characteristics will be described using descriptive analysis, i.e. described as counts and percentages for categorical variables and measures of central tendency (mean, median, SD, and min/max) for continuous variables. Differences between the cohorts will be

assessed using ASD, where an ASD of at least 10% will be considered a meaningful difference. Patients with missing data will be reported as missing and excluded from the comparison for the missing variable. Bivariate statistical significance tests such as Chi-square test for categorical variables and Wilcoxon rank sum test or t-test for continuous variables (depending on distribution of data) will be performed to compare differences in baseline characteristics between the three cohorts. In addition to standardized differences, p-values will be reported. A multi-variable logistic regression model will be constructed for the secondary objective.

Documents

Study, other information

study_1199-0375_ct.gov_form.pdf (404.53 KB)

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)

Ambulatory EMR - OMOP

Data source(s), other

Electronic Medical Records Data (Ambulatory) - US

Data sources (types)

Other

Data sources (types), other

IQVIA’s GE Centricity EMR database from October 2013 to April 2018

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