Investigating idiopathic pulmonary fibrosis in Greece (INDULGE IPF)

First published: 04/01/2017

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS17015

Study ID

44737

DARWIN EU® study

No

Study countries

Greece

Study description

To gain further insight on the characteristics, management, disease progression and the outcomes of patients with IPF, as diagnosed and treated under real-world, clinical practice conditions in Greece. More specifically, this registry will

be used to: Provide a comprehensive clinical picture of IPF, Track access to health care and cost of caring for IPF patients over time, Examine the implementation of treatment guidelines used on patients diagnosed with IPF, according to the existing diagnosis guidelines, Characterization of patients on different treatments. To provide information regarding survival and mortality causes, IPF exacerbations as well as IPF patient co-morbidities including myocardial infarction, CNS infarction, other arterial thromboembolic events, deep vein thrombosis, hemorrhage, gastrointestinal perforation and pulmonary hypertension. Data regarding IPF patient hospitalization will be collected and evaluated with regards to potential respiratory causes, and there will be documentation of treatment patterns and economic aspects. Patients will be followed up for 2 years and information regarding IPF treatment changes since the last visit will be collected.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Georgios Patentalakis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/01/2017

Actual: 17/02/2017

Study start date

Planned: 31/03/2017

Actual: 04/04/2017

Date of final study report

Planned: 30/05/2022

Actual: 29/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Ellas S.A.

Study protocol

1199-0252_protocol_redacted.pdf (647.05 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:

Primary data collection

Study design:

This was a national, multi-center, observational disease registry based on new data from a significant sample size of IPF patients in Greece.

Main study objective:

The main objective of this IPF registry was to gain further knowledge on the characteristics, management, disease progression and outcomes of patients with IPF as diagnosed and treated under real-world, clinical practice conditions in Greece.More specifically, this registry aimed to:

• Provide a comprehensive clinical picture of IPF

• Track access to health care and cost of caring for IPF patients over time

• Examine the implementation of treatment guidelines used on patients diagnosed with IPF, according to the existing diagnosis guidelines

• Characterize patients on different treatments

Furthermore, this registry aimed to provide information regarding survival and mortality causes, IPF exacerbations as well as IPF patient co-morbidities including myocardial infarction, CNS infarction, other arterial thromboembolic events, deep vein thrombosis, hemorrhage, gastrointestinal perforation and pulmonary hypertension. In addition, data regarding IPF patient hospitalization would be collected and evaluated with regards to potential respiratory causes, and there would be documentation of treatment patterns and economic aspects.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Registry

Study drug and medical condition

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Age groups

- Adults (46 to < 65 years)

Estimated number of subjects

300

Study design details

Setting

In order to ensure adequate patient numbers per center and high quality of data, seven (7) University Pulmonology Clinics and Reference Centers of Public Hospital Setting that follow up around 70%-80% of IPF patients within the Greek territory were involved. The registry was scheduled to run for 4 years in total (2 years recruitment +

2 years follow up) (April 2017 to Mar 2021).

Data analysis plan

The nature of the statistical analyses will be exploratory and descriptive. Continuous variables will be listed as median with interquartile and other percentages, and as mean value with standard deviation (SD), along with minimum and maximum values (depending on the underlying distribution). Categorical values will be listed as absolute and relative frequencies. All events during follow up will be described as incidence rates with 95% confidence interval (CI). Stratified analyses will be performed among newly diagnosed patients (< 6 months) as well as patients that were diagnosed in the past (>= 6 months). In case of conflicting results those of the newly diagnosed will be the decisive. Due to limited number of patients and population heterogeneity, no comparison between treatments can be done and no causal relationship conclusion can be derived (no hypothesis testing). Statistical analyses will be performed with IBM SPSS Statistics (Version 19.0).

Documents

Study results

1199-0252_Synosis.pdf (504.27 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), other

IPF registry

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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