IPF Italian observational study (FIBRONET)

First published: 12/07/2016

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Study Ongoing

Administrative details

EU PAS number

EUPAS14067

Study ID

14068

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Long-term data on the natural course of IPF in Italy are scarce. Further, there is limited information on IPF in terms of patient characteristics and disease management. The purpose of the present study is to evaluate the characteristics, management and clinical course of patients with IPF as treated

under real-world in Italian Pulmonary Centres, in terms of symptoms, lung function and exercise tolerance during 12 months of observation. In particular, the study aims to provide information on disease characteristics and treatment modalities (at enrolment) and on disease progression, HRQoL and health care sector-related costs according to the Italian National Health Service (INHS) point of view (during 12 months of observation).

Study status

Ongoing

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

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/06/2015

Actual: 26/06/2015

Study start date

Planned: 17/11/2015

Actual: 17/11/2015

Date of final study report

Planned: 31/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Italia S.p.A.

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

The study aims to provide information on disease characteristics and treatment modalities (at enrolment) and on disease progression, HRQoL and health care sector-related costs according to the Italian National Health Service (INHS) point of view (during 12 months of observation).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

200

Study design details

Outcomes

To describe the clinical course during 12 months of observation, in terms of:• symptoms • lung function (VC, FVC, FEV1, TLC, DLCO, pO2, pCO2)• exercise tolerance (6-minute walk distance test). Description of characteristics of IPF patients in terms of:key demographic data,IPF risk factors,comorbiditie,IPF disease severity and manifestation,methods used for IPF diagnosis,IPF treatment modalities,to describe the frequency of exacerbations,to describe HRQoL variation, measured with SGRQ, EuroQol 5-dimension 5-level descriptive system and EQ VAS,to describe health care sector-related costs

Data analysis plan

The statistical analysis will be performed on all evaluable patients who enter the study and meet the inclusion criteria. Patients with missing values will not be excluded from the analysis, their data will not be replaced, frequency of missing data will be given for all analyzed variables. Descriptive analysis will be composed of means, medians, quantiles, proportions (with their respective 95% confidence intervals, CI) and contingency tables according to the nature of the variables. As a dispersion measurements, the standard deviation and the interquartile range will be calculated. All events during follow-up will be described as incidence rates with 95% CI.

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 sources (types)

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