Observational Analysis on the Socio-economic Impact of Idiopathic Pulmonary Fibrosis (IPF) in Spain (OASIS-IPF)

First published: 01/06/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS19387

Study ID

39833

DARWIN EU® study

No

Study countries

Spain

Study description

IPF is a chronic, progressive fibrosing interstitial pneumonia of unknow cause. There is no evidence on the costs of patients with IPF in Spain based on actual clinical practice. The main objective is to compare the economic impact of IPF according to FVC % predicted level (FVC<50%, FVC 50-80%, FVC>80%), in adult patients through estimation of annual direct and indirect costs associated with the disease at in one year. Secondary Objectives: - To estimate the QoL of the patients with IPF according to FVC % predicted level, through SGRQ and EQ-5D-5L questionnaires and the Barthel Index at baseline. - To explore the determinants of costs and QoL in patients with IPF according to FVC % predicted level. - To characterize acute IPF exacerbations along one year (frequency and cost) according to FVC % predicted level at baseline. - To describe the variation of costs and QoL with IPF progression (according to the FVC deterioration). - To explore the impact of disease on the patient’s caregiver through Zarit Burden Interview questionnaire at 6 and 12 month. Non-interventional multicenter study based on newly collected data of Idiopathic Pulmonary Fibrosis patients followed-up for one year in secondary care settings (Pulmonology Services). IPF patients will be enrolled in a consecutive manner over a period of 6 month. Based on the investigation into the viability of recruitment, we expect to include 200 patients approximately. Inclusion criteria: - Female and male patients ≥40 years of age. - Patients diagnosed with IPF according to last ATS/ERS/JRS/ALAT IPF guideline for diagnosis and management consensus. - Written informed consent prior to participation. Exclusion criteria: - Inability for the patient to understand or complete the written Informed Consent or patient questionnaires or to understand Spanish. - Current participation in any clinical trial. - Patients for whom further follow-up is not possible at the enrolling site.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 25 centres are involved in the study

Contact details

Study institution contact

Alba Ramon alba.ramon@boehringer-ingelheim.com

Study contact

alba.ramon@boehringer-ingelheim.com

Primary lead investigator

María Jesús Rodríguez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/10/2016

Actual: 14/10/2016

Study start date

Planned: 30/11/2017

Actual: 18/12/2017

Data analysis start date
Planned: 04/11/2019

Actual: 23/12/2019

Date of final study report
Planned: 16/09/2020

Actual: 17/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Spain S.A.

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:

Healthcare resource utilisation

Data collection methods:

Primary data collection

Main study objective:

- To compare the economic impact of Idiopathic Pulmonary Fibrosis (IPF) according to FVC % predicted level (FVC<50%, FVC 50-80%, FVC>80%), in adult patients through estimation of annual direct and indirect costs associated with the disease at in one year.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pharmacoeconomic study

Study drug and medical condition

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Short description of the study population

Patients with Idiopathic Pulmonary Fibrosis (IPF).

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

200

Study design details

Outcomes

Main sociodemographic and clinical variables will be collected in order to describe population included in the study. In order to compare the economic

impact of Idiopathic Pulmonary Fibrosis (IPF) according to FVC % predicted level (FVC<50%, FVC 50-80%, FVC>80%) in adult patients through estimation of annual direct and indirect costs associated with the disease. Estimate the QoL:- SGRQ - EQ-5D-5L questionnaires - Barthel index.Explore the determinants of costs and to estimate the direct and indirect costs.The number of exacerbation events observed during the study period Explore the impact of the disease on the patient’s caregiver:- Zarit Burden Interview

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Data analysis plan

- A descriptive analysis of all variables collected will be performed.- For each patient, the annual direct costs, and indirect costs will be quantified. - Mean, standard deviation, % confidence interval of the mean, median and interquartile range will be calculated for the scores obtained with the SGRQ questionnaire collected and absolute and relative frequencies will be calculated for the scores obtained with the EQ-5D-5L questionnaire collected.- If sample size allows for it, bivariate and multivariate analysis will be performed in order to explore the variables impacting costs and QoL for each study subpopulation. - Descriptive analyses will be carried out of the total number of acute IPF-related exacerbations as well as the use of resources and costs associated with the events according to the predicted FVC at the time of inclusion- Descriptive analyses will be carried out of direct and indirect costs and patient QoL according to the change in FVC over one year.

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