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

**First published:** 01/06/2017

**Last updated:** 10/03/2021

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/39833

**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.

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**Study status**

Finalised

## Research institutions and networks

## Institutions

Multiple centres: 25 centres are involved in the study

## Contact details


**Study institution contact**

Alba Ramon

Study contact

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**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

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**Study start date**

Planned: 30/11/2017

Actual: 18/12/2017

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**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).

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**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)

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**Special population of interest**

Other

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**Special population of interest, other**

Idiopathic Pulmonary Fibrosis (IPF) patients

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**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

## 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