A multicentre, retrospective chart review study to describe the clinical profile of idiopathic pulmonary fibrosis (IPF) patients treated with nintedanib (OFEV®) in real-world practice in Spain (BROAD)

First published: 01/06/2017

Last updated: 31/03/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS19384

Study ID

32078

DARWIN EU® study

No

Study countries

☐ Spain

Study description

The present study has been designed to characterize IPF patients treated with nintedanib (OFEV®) with respect to their clinical profile based on real-world data from January 2016 in Spanish Pulmonology Services. The primary objective of the study is to describe the distribution of patients across different lung function categories (%FVC and DLCO serving as surrogate markers for IPF severity) of IPF patients treated with nintedanib (OFEV®) in routine clinical practice, at the time of treatment initiation. Patients will be classified with regards to the FVC and DLCO serving as surrogates for severity: FVC:- Mild IPF: FVC > 70% predicted - Moderate IPF: FVC 50% to 70% predicted (*)- Severe IPF: FVC < 50% predicted (*) %FVC has been adapted from 55 to 50% to be aligned with nintedanib (OFEV®) clinical trials program. DLCO:- Mild IPF: DLCO >50% predicted- Moderate IPF: DLCO 35% to 50% predicted- Severe IPF: DLCO <35% predicted Non-interventional study based on medical charts of multiple centers, of IPF patients treated with nintedanib (OFEV®). Patients will be characterized at time of treatment initiation (cross-sectional design). IPF patients with a confirmed diagnosis of IPF, who initiated treatment with nintedanib from 01 January 2016, will be selected. Approximately 35 Pulmonology Services of Hospitals in Spain will be the basis for the study. The sites will be distributed across whole Spain and will be selected according to previous experience in clinical trials, named-patient program and access to nintedanib (OFEV®).The participating investigators will review all medical records of their IPF patient’s since 01 January 2016 and select all patients who initiated treatment with nintedanib (OFEV®) in the study period.

Study status

Finalised

Research institutions and networks

Institutions

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Multiple centres: 35 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jose Antonio Rodríguez Portal

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/11/2016

Actual: 15/11/2016

Study start date
Planned: 29/09/2017

Actual: 23/10/2017

Data analysis start date
Planned: 26/03/2018

Actual: 07/06/2018

Date of final study report
Planned: 27/05/2019

Actual: 07/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to describe the distribution of patients across different lung function categories (%FVC and DLCO serving as surrogate markers for IPF severity) of IPF patients treated with nintedanib (OFEV®) in routine clinical practice, at the time of treatment initiation.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

Medicinal product name

OFEV

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Short description of the study population

Idiopathic pulmonary fibrosis (IPF) patients treated with nintedanib (OFEV®) with respect to their clinical profile based on real-world data from Spanish pulmonology Services.

Patients could be included in the study if all of the following criteria were met:
1. The patient is at least 18 years old
2. The patient has IPF diagnosis according to 2011 ATS/ERS/JRS/ALAT IPF guideline for diagnosis and management
3. The patient newly initiated treatment with nintedanib (OFEV®) since 01 January 2016 up to end of data collection date, according to the approved local SmPC.

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

175

Study design details

Outcomes

The primary outcome of the study is the distribution of patients across different lung function categories (%FVC and DLCO serving as surrogate markers for IPF severity) of IPF patients at the time of treatment initiation with nintedanib (OFEV®) in routine clinical practice. To describe demographic and clinical baseline characteristics of IPF patients at time of treatment initiation with nintedanib (OFEV®).

Data analysis plan

Since the study is essentially descriptive the variables included in the study objectives will be analysed with measures of central tendency (mean and median), variability/dispersion (standard deviation and interquartile ranges), absolute and relative frequencies, and ranges. 95% confidence intervals will be provided as appropriate.

Documents

Study results

1199-0295-non-interventional-study-report.pdf (658.69 KB)

Data management

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

Retrospective chart review study

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

Unknown