Non-Interventional study (NIS) Collecting Experiences For IPF in Taiwan (NICEFIT)

First published: 14/07/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS19865

Study ID

28202

DARWIN EU® study

No

Study countries

Taiwan

Study description

This is a non-interventional, multi-center study to collect data from patients with idiopathic pulmonary fibrosis (IPF) in clinical practice in Taiwan. The study will be carried out at 10 medical centers, the expert centers where IPF patients

are mainly managed in Taiwan.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

John.chang@boehringer-ingelheim.com

Primary lead investigator

John Chang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/06/2017

Actual: 19/06/2017

Study start date

Planned: 07/08/2017

Actual: 07/08/2017

Data analysis start date

Planned: 01/04/2020

Date of interim report, if expected
Planned: 01/11/2018

Actual: 15/11/2018

Date of final study report
Planned: 30/06/2020

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The primary objective is to characterize the IPF population in Taiwan with regard to their clinical course under clinical practice conditions in Taiwan. The secondary objectives are to understand the clinical characteristics and quality of life of IPF population in Taiwan.

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 (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

100

Study design details

Outcomes

Annual change of lung function. (i.e. FVC, DLco, SpO2, TLC and IC), AE-IPF, SGRQ, CAT, 6MWT and mortality

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Data analysis plan

A Data Management Plan (DMP) and Statistical Analysis Plan (SAP) will be prepared to describe all processes, variables, and specifications for data collection, cleaning, validation, and analyses. The study is essentially descriptive. All patients who have signed the informed consent and fulfilled study criteria will be included in the main analysis. The variables included in the study objectives will be analyzed with measures of central tendency (mean and median), variability/dispersion (standard deviation and interquartile ranges), distributions of absolute and relative frequencies, and 95% confidence intervals, as appropriate. Mortality will be analyzed by Kaplan-Meier estimates.For analysis of primary and secondary outcomes (spirometry tests, SGRQ, CAT, and 6MWT), imputation will be permitted, if deemed appropriate and on a case-by-case basis, depending on the extent and distribution of missing values, and will be described in the SAP.

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