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

First published: 14/07/2017

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Study Finalised

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

Finalised

Contact details

Study institution contact

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Study contact

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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

Actual: 05/02/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer-Ingelheim

Study protocol

1199-0303_CTP_final-rule_Redacted.pdf (316.82 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

1199-0303; NCT03242759

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

non-interventional multi-center study

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

Medicinal product name

OFEV

Study drug International non-proprietary name (INN) or common name

NINTEDANIB

Anatomical Therapeutic Chemical (ATC) code

(L01XE31) nintedanib

nintedanib

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Short description of the study population

idiopathic pulmonary fibrosis (IPF) patients

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

Setting

Clinical practice in Taiwan.

Outcomes

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

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.

Summary results

Conclusion

This first long-term, real-world study provides the efficacy and safety outcomes of IPF patients following the routine management in Taiwan and finds out that the decline in lung functions is lessened following the treatment of anti-fibrotic drugs. However, the incidence of acute exacerbation is still high in comparison with Western countries and other Asian studies. The ways to prevent acute exacerbation and improve the quality of life in IPF patients warrant further consideration.

Documents

Study results

1199-0303_Synopsis.pdf (295.75 KB)

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