Non-Interventional Collecting Evidences For ILD in Taiwan: Optimized Novel Therapy (NICEFIT ON)

First published: 23/10/2020

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Study Planned

Administrative details

EU PAS number

EUPAS37649

Study ID

37650

DARWIN EU® study

No

Study countries

☐ Taiwan

Study description

The primary objective is to characterize the long-term treatment outcome of nintedanib for IPF/SSc-ILD/PF-ILD population regarding the disease course under the clinical practice in Taiwan. The secondary objective is to discover diagnostic/prognostic factors for patients with IPF/SSc-ILD/PF-ILD.

Study status

Planned

Research institutions and networks

Institutions

National Taiwan University Hospital (NTUH)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hao-Chien Wang

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/06/2019

Actual: 30/06/2016

Study start date
Planned: 03/11/2020

Date of final study report
Planned: 31/12/2025

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:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The primary objective is to characterize the long-term treatment outcome of nintedanib for IPF/SSc-ILD/PF-ILD population regarding the disease course under the clinical practice in Taiwan.

Study drug and medical condition

Name of medicine

OFEV

Medical condition to be studied

Idiopathic pulmonary fibrosis

Interstitial lung disease

Additional medical condition(s)

SSc-associated ILD

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

500

Study design details

Outcomes

(to be analyzed per cohort of IPF, SSc-ILD, or PF-ILD) 1. Annual percentage of decline from baseline in FVC (%) 2. Annual decline from baseline in DLco (%) 3. Annual decline from baseline in resting and exercise SpO2 (%), 1. Time to first acute exacerbation of IPF, or time to ILD worsening for SSc-ILD/PF-ILD after study enrollment 2. Annual change from baseline in SGRQ (for IPF) or K-BILD (for other ILDs) 3. Annual change from baseline in CAT 4. Annual change from baseline in 6MWT 5. Annual change from baseline in Berlin questionnaire 6. Change from baseline in quantification of biomarkers 7. Mortality

Data analysis plan

Descriptive analyses will be performed to summarize patients' baseline characteristics, lung/liver function, the time to exacerbation for IPF/ILD worsening, and the results of questionnaires, etc. Continuous variables include number, mean, median, standard deviation (SD), range (minimum and maximum value), and 95% confidence intervals (CI). Categorical variables will be reported as frequency and percentage. Besides, comparative analysis for baseline characteristics will be conducted between nintedanib/non-nintedanib cohorts.

Documents

Study publications

Wells AU, Flaherty KR, Brown KK, Inoue Y, Devaraj A, Richeldi L, Moua T, Cresta…

George PM, Spagnolo P, Kreuter M, Altinisik G, Bonifazi M, Martinez FJ, Molynea…

Richeldi L, du Bois RM, Raghu G, Azuma A, Brown KK, Costabel U, Cottin V, Flahe…

Distler O, Highland KB, Gahlemann M, Azuma A, Fischer A, Mayes MD, Raghu G, Sau…

Flaherty KR, Wells AU, Cottin V, Devaraj A, Walsh SLF, Inoue Y, Richeldi L, Kol…

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