Investigating Trends in Quality of Life in Patients with Idiopathic Pulmonary Fibrosis (IPF) Under Treatment with Nintedanib (QUALIFY IPF)

First published: 08/10/2018

Last updated: 19/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS25664

Study ID

44734

DARWIN EU® study

No

Study countries

Greece

Study description

Multi-center, non-interventional, prospective cohort study aiming to enroll 120 IPF patients receiving treatment with nintedanib in a consecutive manner from 10-12 reference centers across Greece.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Georgios Patentalakis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2018

Actual: 15/06/2018

Study start date

Planned: 05/03/2019

Actual: 05/03/2019

Date of final study report

Planned: 31/12/2023

Actual: 05/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

BOEHRINGER INGELHEIM ELLAS SA

Study protocol

1199-0355_ctp_Redacted.pdf (748.74 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

1199.355

NCT03710824

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Other

If ‘other’, further details on the scope of the study

QoL evaluation

Data collection methods:

Primary data collection

Study design:

National, multicentre, non-interventional, prospective cohort study

Main study objective:

To evaluate the HRQoL changes of IPF patients treated in current clinical practice in Greece with nintedanib over a 52-weeks period

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

Patients with IPF Under Treatment with Nintedanib

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

240

Study design details

Setting

Data of 180 newly diagnosed IPF patients enrolled from 10 University Pulmonology Clinics and Reference Centres of the Public Hospital Setting across Greece were collected. Hospital Pulmonary Clinics acted as coordinating sites of the study. All included sites were reference centres for IPF, both in Athens and the rest of Greece, so that patients enrolled would constitute a representative population of IPF patients in Greece.

Outcomes

Mean change from baseline in HRQoL in patients under treatment with nintedanib over 52 weeks follow-up period, Change from baseline of dyspnoea burden as measured by mMRC questionnaire Mean change from baseline of cough burden as measured by the cough - VAS Percentage of adhered patients to nintedanib treatment Mean change from baseline of anxiety as measured by the GAD-7 questionnaire. Percentage of patients that use LTOT over the 52 weeks follow up period

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Data analysis plan

The nature of the statistical analyses will be exploratory and descriptive.

Summary results

In conclusion, in the QUALIFY study, newly diagnosed IPF patients being treated with nintedanib under real-life conditions showed deterioration in the overall self-reported HRQoL, in line with the progressive nature of the disease Moreover, no apparent effect on the delay of deterioration was implicated in the overall HRQoL, except from a modest effect in the symptoms burden. Nevertheless, future analyses designed based on the patients' disease clinical characteristics including severity at baseline as well as disease progression over time upon treatment with nintedanib may help to further elucidate nintedanib's potential effect on the HRQoL of

patients with IPF.

Documents

Study results

1199-0355_Synopsis.pdf (483.06 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