Real-World Medication Adherence Trajectories to Nintedanib among Idiopathic Pulmonary Fibrosis Patients

First published: 27/08/2021

Last updated: 16/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS42653

Study ID

42912

DARWIN EU® study

No

Study countries

United States

Study description

This is a non-interventional cohort study using existing administrative data from the U.S. Medicare program. This study has two objectives: - Identification of adherence trajectories of nintedanib among Idiopathic Pulmonary Fibrosis (IPF) patients. - Understanding characteristics of patients within each nintedanib adherence trajectory among IPF patients.

Study status

Finalised

Research institutions and networks

Institutions

Medicus Economics

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Mona Nili

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/04/2021

Actual: 28/04/2021

Study start date
Planned: 23/08/2021

Data analysis start date
Planned: 23/08/2021

Date of final study report
Planned: 31/12/2022

Actual: 08/11/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1199-0471_Prot_SAP_redacted.pdf (304.46 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Other study registration identification numbers and links

1199-0471; NCT05022784

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

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

Medication Adherence

Data collection methods:

Secondary use of data

Study design:

Non-interventional, retrospective cohort study

Main study objective:

Identification of adherence trajectories of nintedanib use among patients with idiopathic pulmonary fibrosis.

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

(L01EX09) nintedanib

nintedanib

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Short description of the study population

Community-dwelling Medicare beneficiaries with IPF who initiate treatment with nintedanib.

Age groups

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

Estimated number of subjects

1.500

Study design details

Outcomes

Adherence trajectories based on monthly proportion of days covered (PDC)

Data analysis plan

This study will use group-based trajectory modeling (GBTM) method to identify trajectories of adherence. The output of GBTM will include estimated probabilities of cluster membership for each individual and an estimated trajectory curve over time for each cluster. Best final model will be selected based on statistical and clinical considerations. The association between membership of trajectories and characteristics (e.g. sociodemographics,

clinical, economic burden) will be assess by using polynomial logistic regression models.

Summary results

Among included population, mean age was 75.4±5.5 years. 1098 (61.1%) were male, and 1638 (91.1%) were non-Hispanic white. The best-fitting GBTM had five adherence trajectory groups: highly adherent, medium adherent, gradual decliners, intermediate decliners, and rapid-decliners. Some of patients' characteristics (e.g., age (p-value<0.001) and sex (p-value<0.001)) were significantly different among adherence trajectories.

Documents

Study results

1199-0471_Synopsis.pdf (182.47 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 source(s), other

administrative data from the U.S. Medicare program

Data sources (types)

Administrative healthcare records (e.g., claims)

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