Assessment of the Dose Reduction and Discontinuation Associated With Anti-Fibrotic Medications in Patients With Idiopathic Pulmonary Fibrosis

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001179

Study ID

1000001179

DARWIN EU® study

No

Study countries

United States

Study description

The overarching aim of our study is to assess the incidence of dose reduction and discontinuations for pirfenidone and nintedanib.

Study status

Finalised

Contact details

Study institution contact

Boehringer Ingelheim clinicaltrialregistry@boehringer-ingelheim.com

Study contact

clinicaltrialregistry@boehringer-ingelheim.com

Primary lead investigator

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/04/2023

Study start date

Actual: 18/04/2023

Date of final study report

Planned: 01/12/2027

Actual: 14/07/2023

Study protocol

Prot_SAP_1199-0526_redacted.pdf (305.43 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Other study registration identification numbers and links

1199-0526; NCT05779007

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Non-interventional, retrospective cohort study

Main study objective:

1. Primary aim -To assess average daily dose, and corresponding dose reduction/interruption patterns in nintedanib and pirfenidone initiators separately at 6-and 12-months post initiation.
2. Secondary aim -To assess drug discontinuation patterns in nintedanib and pirfenidone initiators separately at 6-and 12 months post-initiation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OFEV

ESBRIET

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

NINTEDANIB

PIRFENIDONE

Anatomical Therapeutic Chemical (ATC) code

(L04AX05) pirfenidone

pirfenidone

Population studied

Short description of the study population

Patients with Idiopathic Pulmonary Fibrosis

Study design details

Outcomes

The main outcomes for the study were incidence of sub-optimal dosing and discontinuation, calculated separately for pirfenidone and nintedanib. For each patient, average daily dose was calculated separately in each month in the post-index period.

Documents

Study results

1199-0526_Synopsis.pdf (424.98 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

Optum claims database

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