Observational, multicentre, prospective, real-world post-authorization safety study describing the achievement of nintedanib-associated DIArrhoea control after 12 weeks of follow-up in patients with idiopathic puLmonary FIBrosis (IPF) and progressive pulmonary fibrosis (other than IPF) in Spain: the DIALFIB study

First published: 05/09/2023

Last updated: 19/10/2026

Study | Finalised

Administrative details

EU PAS number

EUPAS106524

Study ID

106525

DARWIN EU® study

No

Study countries

Spain

Study description

This study aims to describe the proportion of patients that achieve diarrhoea control after 12 weeks of follow-up among patients with IPF and other PPF having a first episode of nintedanib-associated diarrhoea in real world settings in Spain.

It is expected that the study findings would suggest potential alternatives to address this problem and guide future studies aiming to prove the effectiveness of anti-diarrhoea treatments in this population.

Study status

Finalised

Research institutions and networks

Institutions

Clinical Pharmacology Department, Area del Medicament, Hospital Clínic de Barcelona

Spain

First published: 29/03/2010

Last updated: 24/08/2023

Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

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Primary lead investigator

Sellarès Jacobo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/06/2023

Actual: 05/06/2023

Study start date

Planned: 30/04/2024

Actual: 30/04/2024

Data analysis start date

Planned: 30/05/2025

Actual: 20/06/2025

Date of final study report

Planned: 27/11/2025

Actual: 13/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Spain

Study protocol

Protocol_and_Protocol_Amendment_03_Dec_2025__Redacted.pdf (1.62 MB)

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

1199-0545

NCT06200714

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Other

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

Nintedanib associated diarrhoea control

Data collection methods:

Primary data collection

Study design:

Observational, non-interventional, multicentre, and prospective, real-world post authorization safety study (PASS)

Main study objective:

To describe the proportion of patients who achieve diarrhea control while taking a nintedanib dose of 150 mg bid at 12-week follow up in patients with IPF and other PPF reporting a first episode of nintedanib-associated diarrhea at study baseline.

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

Diarrhoea

Population studied

Short description of the study population

All patients diagnosed with IPF and PPFs who reported a first episode of diarrhoea while being treated with nintedanib optimal dose (150 mg twice per day [bid])

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

Hospital settings in Spain

Outcomes

Achievement of diarrhea control (yes/no), defined as the passage of less than 3 loose or liquid stools in a 24-hour period (loose or liquid stools defined as stools with a BSFS of 6 or 7 points (17))while being treated with 150 mg bid of nintedanib, at 12-week follow-up.
1. Absolute change in the proportion of patients taking optimal nintedanib dose (150 mg bid) at 12-week follow-up referent to baseline
2. Absolute change in BSFS score at week 12 follow-up referent to baseline
3. Absolute change in number of stools per day at 12-week follow-up referent to baseline
4. Absolute change in current body weight (in kilograms) at 12-week And 6 more

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Data analysis plan

Descriptive statistics will be presented as absolute (counts) and relative frequencies (proportions) for categorical variables, and mean, standard deviation, median, 25 and 75 quartiles, and minimum, and maximum values for continuous variables.

Summary results

During the recruitment period, 18 patients were included in the study. One patient was subsequently excluded due to not fulfilling the eligibility criteria, resulting in a final analysed population of 17 patients.

At baseline, the mean (SD) age of the included population (n=18) was 70.28 (6.88) years, and 14 patients (77.78%) were male. Most patients were White 16 (88.89%), followed by Latino 1 (5.56%) and Black 1
(5.56%). Mean (SD) body mass index (BMI) was 28.97 (5.67) kg/m² and mean (SD) body weight was 80.84 (16.68) kg. Regarding smoking status, 13 (72.22%) were ex-smokers, 4 (22.22%) non-smokers, and 1 (5.56%)
smoker.

17 patients were finally eligible and finished the study. Among these eligible patients, the most common comorbidities were arterial hypertension (suffered by 47.06% of patients), sleep apnoea (29.41%), emphysema (29.41%), diabetes (23.53%) and coronary heart disease (23.53%).

Of the 17 eligible patients, 70.59 % achieved diarrhoea control while taking a nintedanib dose of 150 mg twice daily (bid) at the 12-week follow-up. 76.47% of patients were taking the optimal nintedanib dose at the 12-week follow-up. BSFS score in the 12-week follow-up, as compared to the baseline visit, presented a mean (SD) difference of 1.76 (1.60). During this period, mean (SD) change for number of stools was -2.09
(1.27) stools per day. Mean body weight in kilograms presented a mean

Documents

Abstract of study report

1199-0545_Synopsis.pdf (380.85 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)

Electronic healthcare records (EHR)

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