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: 16/02/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106525

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

Planned

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

Study institution contact

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Study contact

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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

Data analysis start date

Planned: 30/05/2025

Date of final study report

Planned: 28/11/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Spain

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 list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Other

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

Nintedanib associated diarrhoea control

Data collection methods:

Primary data collection

Main study objective:

To describe the proportion of patients who achieve diarrhoea 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 diarrhoea at study baseline.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational new data PASS

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

100

Study design details

Outcomes

Achievement of diarrhoea 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

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.

Data management

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