An active surveillance to monitor the real world safety in Indian patients prescribed nintedanib for the treatment of Idiopathic Pulmonary Fibrosis

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Study Finalised

Administrative details

EU PAS number

EUPAS17055

Study ID

40189

DARWIN EU® study

No

Study countries

☐ India

Study description

This is an active surveillance study to monitor the real workd safety of nintedanib in Indian patients with Idiopathic Pulmonary Fibrosis. The safety of nintedanib has been assessed in Clinical Trials. Since only 20 patients in India were enrolled in the Inpulsis trials, the safety data on Indian patients is limited. In this active surveillance, the safety of nintedanib in IPF patients will be examined in Indian real world setting.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

NAABI Kolkata, Bhatia Hospital Mumbai, Narayana Hrudayalaya Bangalore, Sterling Hospital Ahmedabad, Hinduja Hospital Mumbai, Ruby Hall Pune, Asthma Bhavan Jaipur, King George Medical University Lucknow, Midland Healthcare and

Research Center Lucknow, The Calcutta Medical Research Institute Kolkata

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pavitra Wagh

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/01/2017

Actual: 21/01/2017

Study start date

Planned: 24/02/2017

Actual: 01/05/2017

Data analysis start date

Planned: 28/02/2017

Actual: 01/05/2017

Date of final study report
Planned: 31/10/2023

Actual: 23/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

clinical-trial-protocol-amendment-01_2.pdf(459.06 KB)

1199-0280-Protocol-V5.pdf(663.7 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Other

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

Safety of nintedanib in IPF patients in Indian real world setting

Main study objective:

The main objective of this study is to examine the safety of nintedanib in IPF patients in Indian real world setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

The design of this active surveillance is of non-interventional nature and will be conducted within the conditions of the approved marketting authorisations

Study drug and medical condition

Name of medicine, other

Nintedanib

Medical condition to be studied

Idiopathic pulmonary fibrosis

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

400

Study design details

Outcomes

The primary outcome is Occurrence of ADRs (serious and non-serious) in nintedanib treated patients & Occurrence of AEs (serious and fatal) in nintedanib treated patients. The secondary outcome is Percentage of patients who require dose reductions and discontinuation due to adverse events.

Data analysis plan

Analyses will be descriptive in nature including means, medians, standard deviation and interquartile range for continuous variables, and frequencies and percentages for binary and categorical variables with the corresponding 95% confidence intervals. For safety outcomes, incidence rates with corresponding 95% confidence intervals will be calculated. Baseline characteristics of consecutive 100 IPF patients not treated with nintedanib will be used to compare the patients profile with the nintedanib users and will allow us to put the safety data of nintedanib into perspective.

Documents

Study results

1199-0280-NIS Report.pdf(224.01 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