An active surveillance to monitor the real world safety in Indian patients prescribed nintedanib for the treatment of locally advanced, metastatic or recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy.

First published: 04/01/2017

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17078

Study ID

40195

DARWIN EU® study

No

Study countries

India

Study description

An active surveillance based on newly collected data. This active surveillance will include 100 consecutive patients with locally advanced, metastatic or recurrent NSCLC and adenocarcinoma histology who have been newly prescribed nintedanib according to approved Indian label at the twenty (20) participating centres and 100 consecutive locally advanced, metastatic or recurrent NSCLC patients of adenocarcinoma histology who have progressed after first line chemotherapy and are planned to be treated with single agent docetaxel from the same centres and during the same time frame. At visit 1, baseline characteristics will be recorded for all patients. Patients who are prescribed nintedanib are suggested to have further visits every 3 weeks for the first 6 visits and every 6 weeks till the discontinuation of the treatment and an additional follow up visit 30 days after the last dose of nintedanib. At each visit ADRs with nintedanib (serious or non-serious) and AEs (serious and fatal) will be recorded. Patients who are treated with single agent docetaxel will not be followed. The patient registration will continue until it is confirmed that 100 patients treated with nintedanib are included in this active surveillance and that baseline characteristics of 100 additional patients planned to be treated with single agent docetaxel at the same centres and during the same time frame are collected, or until a maximum of two years, whichever occurs first.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

HCG Hospital Bangalore, Medica Superspecialty Hospital Kolkata, Sparsh Hospitals & Critical Care (P) Ltd Bhubhaneshwar, Sir Ganga Ram Hospital New Delhi, Manipal Hospitals Bangalore, Apollo Healthcity Hospital Telangana, Zydus Hospital Gujarat, Yashoda Hospital Hyderabad, Mazumdar Shaw Medical Centre Bangalore, SRM-SIMS Tamil Nadu

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: 30/06/2017

Actual: 30/06/2017

Date of final study report

Planned: 31/05/2023

Actual: 27/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

clinical-trial-protocol-revision-01-2016-09-28.pdf (456.72 KB)

1199-0272-Protocol-V-4.pdf (679.49 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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

To evaluate real-world safety of nintedanib in Indian patients with non-small cell lung cancer of adenocarcinoma histology after first line of chemotherapy

Main study objective:

To evaluate real-world safety of nintedanib in Indian patients with non-small cell lung cancer of adenocarcinoma histology after first line of chemotherapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Nintedanib

Medical condition to be studied

Non-small cell lung cancer stage IIIB

Non-small cell lung cancer stage IV

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

200

Study design details

Outcomes

Safety The primary outcome Occurrence of ADRs (serious and non-serious) Occurrence of AEs (serious and fatal), Safety Secondary outcome Percentage of patients who require nintedanib dose reductions and discontinuations 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 NSCLC 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. Whenever patient profiles differ between those treated with combination of nintedanib and docetaxel and single agent docetaxel, cautious interpretation is required when comparing with nintedanib treated populations from other trials / registries.

Documents

Study results

1199-0272-NIS Report.pdf (165.27 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