The special drug use-results survey (All-Case Surveillance) of Ofev® Capsules in patients with Idiopathic Pulmonary Fibrosis (IPF) in Japan

First published: 08/09/2015

Last updated: 15/10/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10891

Study ID

39448

DARWIN EU® study

No

Study countries

☐ Japan

Study description

It is to evaluate the real-world safety and effectiveness of Ofev Capsules treatment in patients with IPF.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rie Ikeda

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 13/07/2015

Study start date
Actual: 31/08/2015

Data analysis start date
Actual: 31/08/2015

Date of final study report
Planned: 31/05/2024

Actual: 25/03/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.,

Study protocol

protocol_1199-0202_Redacted.pdf(494.09 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the real-world safety and effectiveness of Ofev Capsules treatment in patients with IPF

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational, single arm

Study drug and medical condition

Name of medicine

OFEV 100 MG - CAPSULE, SOFT

OFEV 150 MG - CAPSULE, SOFT

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

NINTEDANIB

Anatomical Therapeutic Chemical (ATC) code

(L01EX09) nintedanib

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

5200

Study design details

Outcomes

The frequency of patients with any suspected adverse drug reactions, The absolute change from the baseline in Forced Vital Capacity (FVC) mL at Week 104.

Data analysis plan

Analyses are descriptive in nature including means, standard deviation, Q1, medians, Q3, frequency and percentages. For safety outcomes, incidence rates with corresponding 95% confidence intervals will also be calculated. For the effectiveness outcomes, the point estimate and 95% confidence intervals from statistical models will also be calculated for exploratory purpose.

Documents

Study report

1199-0202--main-part-report_Redacted.pdf(111.18 KB)

Data management

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