Specific Use-result Surveillance of Spiriva Respimat in asthmatics (patients with mild to moderate persistent asthma) (Specific Use-result Surveillance in asthmatics)

First published: 22/06/2017

Last updated: 01/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS19173

Study ID

31192

DARWIN EU® study

No

Study countries

☐ Japan

Study description

The safety of Spiriva® 2.5 µg Respimat® 60 puffs (hereinafter referred to as Spiriva® Respimat®) in patients with mild to moderate persistent asthma under the real-world use was not confirmed in clinical trials.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 25 centres are involved in the study

Contact details

Study institution contact

Yukako Ogi zzCDMJP_PV_PMS@boehringer-ingelheim.com

Study contact

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Primary lead investigator

Yukako Ogi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/05/2014

Actual: 07/05/2014

Study start date

Planned: 01/07/2017

Actual: 25/07/2017

Data analysis start date

Planned: 31/01/2019

Actual: 07/12/2018

Date of final study report

Planned: 31/07/2019

Actual: 25/04/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To investigate the safety and effectiveness of Spiriva Respimat in patients with mild to moderate persistent asthma under the real-world use.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional, observational study based on new data collection

Study drug and medical condition

Medical condition to be studied

Asthma-chronic obstructive pulmonary disease overlap syndrome

Population studied

Short description of the study population

Patients with mild to moderate persistent asthma.

Age groups

- Adolescents (12 to < 18 years)
- 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)

Special population of interest

Other

Special population of interest, other

Asthma-chronic obstructive pulmonary disease overlap syndrome patients

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Estimated number of subjects

180

Study design details

Outcomes

The primary outcome is the absolute and relative (%) frequency of patients with suspected adverse drug reactions (ADRs). Change from baseline in asthma control status

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Data analysis plan

To be analysed only descriptively

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

Unknown