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

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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

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