Specific Use-result Surveillance of Spiriva respimat in asthmatics (patients with severe persistent asthma) (Specific Use-result Surveillance in asthmatics)

First published: 26/05/2015

Last updated: 21/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS9802

Study ID

24759

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 severe 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: 01/06/2014

Actual: 01/06/2014

Study start date

Planned: 01/06/2015

Actual: 01/06/2015

Data analysis start date

Planned: 01/06/2015

Actual: 01/06/2015

Date of final study report

Planned: 01/07/2018

Actual: 06/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.,

Study protocol

0205-0525_non-interventional-study-protocol_Redacted.pdf (539.05 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

Other study registration identification numbers and links

205.525

NCT02489981

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Non-interventional, observational study based on new data collection

Main study objective:

To investigate the safety and effectiveness of Spiriva Respimat in patients with 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

Medicinal product name

SPIRIVA RESPIMAT

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

TIOTROPIUM

Anatomical Therapeutic Chemical (ATC) code

(R03BB04) tiotropium bromide

tiotropium bromide

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients aged ≥ 15 years old with severe persistent asthma who were naive to Spiriva respimat and receive Spiriva Respimat for the first time for the treatment of bronchial asthma on top of at least ICS treatment where safety of Spiriva® 2.5 µg Respimat® 60 puffs under the real-world use was not confirmed in clinical trials.

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 patients

Estimated number of subjects

360

Study design details

Setting

Planned number of subjects: 360

Comparator product: Not applicable

Duration of treatment: 52 weeks

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

Data analysis plan

To be analysed only descriptively

Summary results

Adverse Drug Reactions

Of 340 patients included in the safety set, 21 ADRs were reported in 19 patients. The incidence of ADR was 5.59% (19/340patients). At the primary

system organ class level, the most frequently reported ADRs were ‘respiratory, thoracic and mediastinal disorders’ (10 events in 9 patients, 2.65% [9/340 patients]), and ‘general disorders and administration site conditions’ (4events in 4patients, 1.18% [4/340 patients]). At the preferred term level, the most frequently reported ADRs were thirst, cough, dysphonia(3events in 3patients, 0.88% [3/340patients], each), and dyspnoea (2 events in 2patients, 0.59% [2/340patients]). These ADRs were described in the precaution of the Japanese package insert(expected ADRs).

Effectiveness (the change of asthma control status from baseline at Week 52)

Of 308 patients in the efficacy analysis set, 248 patients had asthma control status at baseline. For those with good control at baseline, 66.67% (8/12 patients) maintained at week 52.For those with insufficient control at baseline, 58.12% (68/117 patients) improved, 17.95% (21/117 patients) maintained, 4.27% (5/117 patients) worsened.

A total of 45 patients worsened asthma control status, that were 24.3% (45/185 patients) in the 185 evaluable patients in the asthma control status at baseline and Week 52.

As described above, there were no notable issues in safety and effectiveness analysis of the surveillance, and any changes in the precaution were not to be considered necessary from the results of the surveillance.

Documents

Study results

0205-0525_Synopsis.pdf (219.28 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

Unknown