Post-marketing surveillance (PMS) on long-term use of tiotropium+olodaterol fixed dose combination (Tio+Olo FDC) 5/5µg in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) in Japan (Japanese Spiolt PMS, long term)

First published: 21/07/2016

Last updated: 17/12/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS14273

Study ID

30567

DARWIN EU® study

No

Study countries

Japan

Study description

Study to assess the long-term safety and effectiveness of Spilolto in Japanese patients with COPD in real-world setting.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 200 centres are involved in the study

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

Planned: 18/09/2015

Actual: 18/09/2015

Study start date

Planned: 23/08/2016

Actual: 23/08/2016

Data analysis start date

Planned: 23/08/2016

Actual: 23/08/2016

Date of final study report

Planned: 30/06/2019

Actual: 11/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Study protocol

Synopsis-1237-34.pdf (93.31 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:

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

Study design:

Non interventional cohort study with follow up of 52 weeks. (Observational)

Main study objective:

Study to assess the long-term safety and effectiveness of Spilolto in Japanese patients with COPD in real-world setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional, prospective, observational, single arm study

Study drug and medical condition

Medicinal product name

SPIOLTO RESPIMAT

Anatomical Therapeutic Chemical (ATC) code

(R03AL06) olodaterol and tiotropium bromide

olodaterol and tiotropium bromide

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

1. Patients who have been diagnosed with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) by physician and need to be treated co-administration of a long-acting inhalational anticholinergic and a long-acting inhalational β2-agonist to relief of various symptoms associated with the obstructive impairment of airways
2. Patients who were prescribed Tio+Olo FDC 5µg /5µg for the first time

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Age groups

- 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

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

1000

Study design details

Setting

Number of study sites: 199 sites

Duration of observation: 52 weeks or until discontinuation of administration

Registration period: August 2016 to August 2017

Study period: August 2016 to November 2018

Outcomes

Incidence and exposure-time adjusted incidence rate of adverse drug reactions (ADRs). COPD assessment test (CAT) at 12 weeks.

Data analysis plan

Descriptive statistics will be summarized for safety and efficacy. Incidence of adverse drug reactions.Change form baseline in COPD assessment test (CAT) at 12 weeks.Subgroup analyses.

Documents

Study results

1237-0034_Synopsis.pdf (297.33 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

Unknown