A regulatory required non interventional study to monitor the safety and effectiveness of once daily treatment of orally inhaled Vahelva Respimat (Tiotropium + Olodaterol fixed dose combination 2.5µg/2.5µg per puff (2 puffs comprise one medicinal dose)) for Korean patients with COPD (Chronic Obstructive Pulmonary Disease) (Vahelva Respimat regulatory Post-marketing Surveil)

First published: 29/08/2016

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14956

Study ID

48428

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

To monitor the safety profile and effectiveness of Vahelva Respimat in Korean patients with COPD in a routine clinical practice setting

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hyelin Lee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2016

Actual: 14/12/2016

Study start date

Planned: 30/09/2016

Actual: 19/12/2016

Date of final study report

Planned: 30/06/2022

Actual: 30/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

1237.6

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)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

Outcomes pertaining to safety will be presented as incidence rates of adverse events

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Vahelva Respimat

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with chronic obstructive pulmonary disease received treatment with orally inhaled vahelva respimat under routine clinical practice in Korea.

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)

Special population of interest

Hepatic impaired

Other

Renal impaired

Special population of interest, other

Patients with chronic obstructive pulmonary disease

Estimated number of subjects

3000

Study design details

Data analysis plan

Descriptive analysis will be performed.

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)

Disease registry

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