Safety profile of Tiotropium + Olodaterol used as maintenance treatment in COPD patients in Taiwan: a non-interventional study based on the Taiwan National Health Insurance (NHI) data (1237-0109)

First published: 17/05/2022

Last updated: 04/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS47368

Study ID

49764

DARWIN EU® study

No

Study countries

☐ China

Study description

To estimate the incidence of safety outcomes in patients with COPD who initiated Tiotropium / Olodaterol (Tio/Olo)

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Shenqi Kong

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/06/2021

Actual: 17/06/2021

Study start date

Planned: 15/08/2022

Actual: 30/09/2022

Date of final study report

Planned: 23/06/2023

Actual: 09/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim (China) Investment Co., Ltd

Study protocol

1237-0109_clinical trial protocol_version01_2022-05-11.pdf (439.46 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To estimate the incidence rate of safety outcomes in Chinese patients with COPD who initiated Tio/Olo

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Spiolto Respimat (Tiotropium + Olodaterol)

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

OLODATEROL

TIOTROPIUM

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

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)

Estimated number of subjects

4000

Study design details

Outcomes

Primary outcomes - Outcome type: Primary - Outcome Name: Incidence rate of adverse events in patients with COPD treated with Tio+Olo - Time Frame: 2014~2019 - Safety Issue (Yes/No): Yes,
Secondary outcomes - Outcome type: Secondary - Outcome Name: Baseline characteristics of patients who initiated Tio+Olo or other LAMA/LABA - Time Frame: 2014~2019 - Safety Issue (Yes/No): No

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Data analysis plan

All variables, including patient characteristics, baseline measures, and outcomes, will be analysed descriptively.
• For all analyses, variables will be reported as follows: Continuous variables (e.g. age) will be presented as means (with standard deviation, SD) and/or

medians (with interquartile range, IQR), minimum, maximum.

• Categorical variables (e.g. sex) will be presented as absolute and relative frequencies.

Absolute standardized differences (ASDs) will be used to compare the characteristics between the two groups, in which a >0.1 ASD indicates a meaningful difference.

The standardized difference will be used as a parameter to quantify the between-group differences for each clinical attribute. This is metric is commonly used in studies utilizing secondary health data, in which a standardized difference of larger than 0.1 indicates a meaningful difference with respect to the clinical attribute between the two study groups.

Documents

Study report

1237-0109 final CTR 20230609.pdf (262.39 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 source(s), other

NHIRD, China

Data sources (types)

Other

Data sources (types), other

Data sources include Taiwan NHI, Taiwan cancer registry (TCR) and Taiwan Mortality Data.Through the services provided by the Health and Welfare Data Science Center (HWDSC) of the Department of Statistics, researchers may access a wide range of health and welfare data, including claims, mortality (with cause of death) and Taiwan Cancer Registry (TCR).

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