Effectiveness of Maintenance Treatment with Tiotropium + Olodaterol in Comparison to Inhaled Corticosteroids + Long-acting β2 agonists in COPD patients in Taiwan: a non-interventional study based on the Taiwan National Health Insurance (NHI) data. (1237-0110)

First published: 18/05/2022

Last updated: 25/09/2026

Study Finalised

Administrative details

EU PAS number

EUPAS47389

Study ID

49767

DARWIN EU® study

No

Study countries

China

Study description

To compare the risk of exacerbations between initiators of Tiotropium / Olodaterol (Tio/Olo) and inhaled corticolsteroids / long-acting β2-agonists (ICS/LABA) in a real world setting

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: 03/07/2023

Actual: 14/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim (China) Investment Co., Ltd

Study protocol

1237-0110_ctp_Redacted.pdf (2.08 MB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Other study registration identification numbers and links

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:

Combined primary data collection and secondary use of data

Main study objective:

To compare time to the first moderate or severe COPD exacerbations between initiators of Tio/Olo and ICS/LABA in a real world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Tiotropium + Olodaterol

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

4.978

Study design details

Outcomes

Primary outcomes - Outcome type: Primary - Outcome Name:Time to the first moderate or severe COPD exacerbations after index date - Time Frame: 2014~2019 - Safety Issue (Yes/No): No, Secondary outcomes Time to triple

therapy escalation after index date,Incidence rate of triple therapy initiation (first event per patient),Time to the first hospitalization for community-acquired,Annualized rate of prescriptions of rescue medications after the index date,Annualized rate of moderate or severe COPD exacerbation after the index date Time Frame: 2014~2019

Data analysis plan

All variables, including patient characteristics, baseline measures, and outcomes, will be analyzed 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 after propensity score matching, in which a >0.1 ASD indicates a meaningful difference.

Documents

Study results

1237-0110_Synopsis.pdf (567.93 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

NHI 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