Early Intervention Efficacy of Tiotropium/Olodaterol Compared to Tiotropium in Chronic Obstructive Pulmonary Disease (COPD) (Early Intervention Efficacy in COPD)

First published: 12/02/2020

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS33426

Study ID

33674

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This study aims to evaluate the time to escalation to triple therapy among the Japanese Chronic obstructive pulmonary disease (COPD) patients newly initiating therapy with a combination of Olodaterol and Tiotropium (herein referred to as Tio/Olo) using real world data.

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Shigeo Muro

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 19/07/2019

Study start date
Actual: 28/09/2015

Date of final study report
Planned: 30/05/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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

ClinicalTrials.gov Identifier: NCT04249310 (https://www.clinicaltrials.gov/ct2/show/NCT04249310?term=Spiolto&draw=3&rank=19)C

Study ID Numbers: 1237-0100

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the time to escalation to triple therapy among the Japanese Chronic obstructive pulmonary disease (COPD) patients newly initiating therapy with a combination of Olodaterol and Tiotropium (herein referred to as Tio/Olo) using real world data.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

1856

Study design details

Outcomes

Time to Long-Acting Muscarinic Antagonists (LAMA)/Long-Acting Beta-Agonists (LABA)/Inhaled Corticosteroid (ICS) triple therapy initiation among initiators of Tio/Olo vs. initiators of Tio, Time to First Moderate or Severe COPD ExacerbationsNumber of Moderate or Severe COPD Exacerbations

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Data analysis plan

For demographic and lifestyle variables, the value recorded on the cohort entry date will be reported, otherwise the most recent known value will be reported. Presence of comorbidities and use of concomitant medication use will be determined based on whether they ever occurred within the 180-day baseline period preceding the index date. Rates of triple therapy use for each treatment group will be reported as the number of events divided by the total number of person-years at risk during follow-up. Risk of triple therapy for each treatment group will be reported as the number of events divided by the total number of patients at risk. Among both the basic propensity score matched and high dimensional propensity score matched cohort, Cox regression will be used to estimate the hazard ratios and 95% CI for Tiotropium/Olodaterol compared to patients treated with Tiotropium during follow-up for time-to-first triple therapy initiation using an intention-to-treat censoring approach.

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)

Administrative healthcare records (e.g., claims)

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