Effectiveness and Safety of Maintenance Treatment with Combination of Tiotropium and Olodaterol in comparison to Maintenance Treatment with a Combination of Inhaled Corticosteroids, Long-acting β2 Agonists and Long-acting Muscarinic Antagonists in COPD Patients

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Study Planned

Administrative details

EU PAS number

EUPAS31932

Study ID

31933

DARWIN EU® study

No

Study countries

United States

Study description

The treatment of COPD involves multiple therapies, including long-acting β2 agonists (LABA) (with and without inhaled corticosteroids (ICS) and long-acting muscarinic antagonists (LAMA), with combinations of these drugs now formulated into single inhalers. There are recommendations to restrict triple therapy use further, to only patients who are likely to respond to ICS (such as those with asthma-COPD overlap or patients with high risk of exacerbations and elevated blood eosinophils. There is an increasing body of evidence suggesting that ICS are particularly effective at reducing the incidence of COPD exacerbations in patients only with a very high blood eosinophil concentration, but not in normal levels. Hence there is a clear need for better evidence on specific patient populations upon which to base treatment recommendations. This non-interventional study aims to assess the comparative effectiveness of combination Tiotropium and Olodaterol (Tio+Olo) (FDC) compared to combination LAMA/LABA and ICS (fixed or open).

Study status

Planned

Research institutions and networks

Institutions

HealthCore

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daina Esposito

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/05/2019

Actual: 22/05/2019

Study start date

Planned: 01/11/2019

Date of final study report

Planned: 21/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer ingelheim International GmbH

Regulatory

Was the study required by a regulatory body?

No

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:

Effectiveness study (incl. comparative)

Main study objective:

The primary objective is to compare the effectiveness of new use of maintenance therapy initiation with the combination treatment Tiotropium and

Olodaterol (Tio+Olo) compared with new use of LABA/LAMA/ICS combination in COPD as the time to the first COPD exacerbation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AL06) olodaterol and tiotropium bromide

olodaterol and tiotropium bromide

(R03AA) Alpha- and beta-adrenoreceptor agonists

Alpha- and beta-adrenoreceptor agonists

(R03B) OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

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

Severe exacerbation as hospitalization with a principal discharge diagnosis of COPD.Moderate exacerbation defined as ED visit with a discharge diagnosis of COPD and/or dispensing of an antibiotic and an oral corticosteroid on the same day

Data analysis plan

Patient characteristics at baseline in patients treated with Tio+Olo and patients treated with LABA/LAMA/ICS will be described using standard descriptive statistics. High-dimensional propensity scores including both pre-specified and data-derived variables will then be calculated. We will use fine stratification and reweighting of the exposure propensity score to control for measured covariates. Cox proportional hazard regression model will be used to perform an as-treated analysis that assesses the effect of current use of LABA-LAMA-ICS combination versus the Tio+Olo combination on the risk of a first COPD exacerbation. It will provide an estimate of the hazard ratio (HR) of a COPD exacerbation associated with LABA-LAMA-ICS use relative to Tio+Olo use, along with 95% confidence intervals (CI).

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