Health Care Resource Utilization, Cost and Other Outcomes of Patients Diagnosed with COPD Initiating Tiotropium Bromide/Olodaterol versus Fluticasone Furoate/Umeclidinium/Vilanterol

First published: 03/02/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS43167

Study ID

47843

DARWIN EU® study

No

Study countries

☐ United States

Study description

The purpose of this study is to estimate disease-related and all-cause burden and clinical outcomes of interest following initiation of COPD maintenance therapy with Tiotropium Bromide/Olodaterol(TIO/OLO) or Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI).

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

Clark Brendan

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/04/2020

Study start date
Actual: 26/02/2021

Date of final study report
Planned: 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?

No

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

Not applicable

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Comparative real world outcomes study

Main study objective:

The purpose of this study is to estimate disease-related and all-cause burden and clinical outcomes of interest following initiation of COPD maintenance therapy with TIO/OLO or FF/UMEC/VI.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TIOTROPIUM BROMIDE

OLODATEROL

FLUTICASONE FUROATE

UMECLIDINIUM

VILANTEROL TRIFENATATE

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

11316

Study design details

Outcomes

COPD and/or pneumonia-related total costs, COPD and/or pneumonia-related medical costs COPD and/or pneumonia-related pharmacy costs COPD and/or pneumonia-related inpatient visits COPD and/or pneumonia-related emergency department visits COPD and/or pneumonia-related ambulatory visits COPD and/or pneumonia-related other medical visits COPD exacerbations Severe COPD exacerbations Pneumonia or bronchitis/bronchitis

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Data analysis plan

Stratified propensity score matching, using an exact match on exacerbation history and maintenance naive status followed by a propensity score match on baseline characteristics, to control for possible confounding of the association between the treatment (TIO/OLO or FF/UMEC/VI) and outcomes (e.g. health care resource utilization). Outcomes will be reported as population annualized averages for each cohort to account for the variable follow-up duration.

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