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

PURI

https://redirect.ema.europa.eu/resource/47843

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

Clark Brendan

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 list

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

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