

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

Last updated: 18/12/2025

Study

Finalised

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

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clark Brendan

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

Actual: 14/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

[1237-0113_protocol_SAP_redacted.pdf](#) (1.08 MB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Healthcare resource utilisation

Other

Safety study (incl. comparative)

If 'other', further details on the scope of the study

Comparative real world outcomes study

Study design:

This was a non-interventional study using existing data from commercial enrollees and Medicare Advantage with Part D beneficiaries diagnosed with

COPD who initiated treatment with TIO/OLO or FF/UMEC/VI. The study period was from 01 June 2014 through 31 December 2019.

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

Anatomical Therapeutic Chemical (ATC) code

(R03AL06) olodaterol and tiotropium bromide

olodaterol and tiotropium bromide

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

Comparators

Newly treated with TIO/OLO compared with patients newly treated with FF/UMEC/VI.

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

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.

Documents

Study results

[1237-0113_Synopsis.pdf](#) (256.19 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 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