Comparison of Exacerbation Risk and Health Outcomes in Maintenance Treatment Naïve COPD patients using Stiolto vs. Trelegy

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Study Finalised

Administrative details

EU PAS number

EUPAS48472

Study ID

48473

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this study was to investigate the risk of COPD exacerbations, community acquired pneumonia, and health care utilization and costs in maintenance treatment naïve patients following initiation of COPD therapy with Tiotropium/Olodaterol (TIO/OLO) or Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI)

Study status

Finalised

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

Asif Shaikh

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 29/10/2020

Study start date
Actual: 17/12/2021

Date of final study report
Actual: 06/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1237-0121_CTP_final-rule_Redacted.pdf (819.33 KB)

1237-0121_protocol_SAP_redacted.pdf (819.33 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

1237-0121

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The goal of this study was to investigate the risk of COPD exacerbations, community acquired pneumonia, and health care utilization and costs in maintenance treatment naïve patients treated as first line therapy with TIO/OLO, in comparison to maintenance treatment naïve patients treated with first line therapy, FF/UMEC/VI

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TRELEGY ELLIPTA

Medicinal product name, other

Stiolto

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

Short description of the study population

Patients with chronic obstructive pulmonary disease received treatment with tiotropium/olodaterol or fluticasone furoate/umeclidinium/vilanterol.

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)

Special population of interest

Other

Special population of interest, other

Patients with chronic obstructive pulmonary disease

Estimated number of subjects

5.902

Study design details

Outcomes

Time to first COPD exacerbation (moderate/severe) Rate of moderate and/or severe exacerbation, Time to first hospitalization of community acquired pneumonia COPD and/or pneumonia-related health care resource utilization COPD and/or pneumonia-related health care resource utilization costs All cause health care resource utilization All cause health care resource utilization costs

Data analysis plan

Propensity score matching 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

1237-0121_Synopsis.pdf (376.83 KB)

Data management

Data sources

Data source(s), other

IQVIA database, United States

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