The Role of Inhaler Device in the Treatment Persistence with Dual Bronchodilators in Patients with COPD

First published: 06/08/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS30838

Study ID

30839

DARWIN EU® study

No

Study countries

Spain

Study description

Stiolto® Respimat®, a combination of Olodaterol and Tiotropium Bromide delivered via soft mist inhaler (SMI), was approved in May 2015 in the US and July 2015 in the EU (marketed as Spiolto in the EU). Anoro® Ellipta®, a combination of Umeclidinium and Vilanterol delivered via dry powder inhaler (DPI), was approved in December 2013 in the US and in February 2014 in the EU. Both products are maintenance therapies consisting of a combination of long-acting muscarinic antagonists (LAMA) and long-acting beta agonists (LABA). However, the question of whether different devices (DPI and SMI) play a role in treatment persistence remains to be answered. This study seeks to compare the treatment persistence of two drugs in same drug class (LAMA/LABA as a fixed dose combination FDC) delivered through different devices (a DPI and a SMI) within an administrative claims database in the US.

Study status

Ongoing

Research institutions and networks

Institutions

Aetion

Spain

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Institution **Other** **ENCePP partner**

Contact details

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Study contact

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Primary lead investigator

Jukka Montonen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/02/2019

Actual: 26/02/2019

Study start date

Planned: 10/06/2019

Actual: 10/06/2019

Data analysis start date

Planned: 11/06/2019

Actual: 11/06/2019

Date of final study report

Planned: 30/03/2020

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

Other study registration identification numbers and links

1237-0090

NCT03979807

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

Treatment persistence

Data collection methods:

Secondary use of data

Study design:

New-user cohort design with propensity scores used to match up to 2 Umeclidinium/Vilanterol initiators to each Olodaterol/Tiotropium Bromide initiator.

Main study objective:

The primary objective of the study is to use US claims data to determine relative treatment persistence in using Olodaterol/Tiotropium Bromide delivered with the Respimat soft mist inhaler and Umeclidinium/Vilanterol delivered with the Ellipta dry powder inhaler using a 1:2 propensity score matched analysis.

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

(R03AL03) vilanterol and umeclidinium bromide

vilanterol and umeclidinium bromide

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients with COPD

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

14.719

Study design details

Setting

Data was utilized from Truven MarketScan claims database that captures longitudinal, individual-level administrative claims data from the United States.

Patient identification period was between 17 November 2015 and 31 March 2018.

Outcomes

The primary outcome of interest is discontinuation of index treatment (Olodaterol/Tiotropium Bromide or Umeclidinium/Vilanterol), defined as persistence (i.e. no refill claim within 60 days not involving treatment switch, nor death (allowable grace period) after end of <n> days supply) during follow-up.

Data analysis plan

Among the post-matched cohort, rates of discontinuation of Olodaterol/Tiotropium Bromide or Umeclidinium/Vilanterol will be reported as the number of events divided by the number of person-years at risk.• Discontinuation of Olodaterol/Tiotropium Bromide or Umeclidinium/Vilanterol in the Post-matched CohortAmong the post-matched cohort, risk (proportion of patients) of discontinuation of Olodaterol/Tiotropium Bromide or Umeclidinium/Vilanterol will be reported as the number of events divided by the number of eligible patients at cohort entry date.

Summary results

The rate of discontinuation was 1,826 per 1,000 person-years in the Olo/Tio group compared to 1,647 per 1,000 person-years in the reference group resulting in a rate difference of appr. 179 per 1,000 person-years.
The adjusted hazard ratio of discontinuation associated with Olo/Tio relative to Umec/Vi was 1.11 (95% CI: 1.06-1.16). Different sensitivity analyses did not have a meaningful impact on the results.

Documents

Abstract of study report

1237-0090_Abstract.pdf (153.8 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 source(s), other

Truven MarketScan claims database

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