Characteristics and Treatment Patterns of Patients with Chronic Obstructive Pulmonary Disease (COPD), Initiating Tio+Olo or Other Maintenance Therapies in the US and the UK: A Retrospective Claims Database Study.

First published: 25/10/2019

Last updated: 14/07/2021

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31941

EU PAS number

EUPAS31940

Study ID

31941

DARWIN EU® study

No

Study countries

- [ ] United Kingdom
- [ ] United States

Study description

Chronic obstructive pulmonary disease (COPD) is a common disease characterized by airway obstruction confirmed by spirometry, often including small airway obstruction and emphysema.For patients who are diagnosed with COPD, maintenance treatments often include bronchodilators, primarily long-acting muscarinic antagonists (LAMA), long-acting beta agonists (LABA), and inhaled corticosteroids (ICS) alone or in combination with each other and corticosteroids. Sp(t)iolto® Respimat®, a LAMA+LABA combination, was approved in May 21, 2015 in the US and July 1, 2015 in the EU (marketed as Stiolto in the US and Spiolto in the EU, referred to here as Tio+Olo). Selective prescribing according to patient characteristics, known as channeling, can lead to bias in comparative studies where drugs with similar therapeutic indications are prescribed to groups of patients with prognostic differences. Claimed advantages of a new drug may be distorted if they are channeled to patients with special pre-existing morbidity, with the consequence that disease states can be incorrectly attributed to use of the drug. Therefore, it is important to identify clinical and socio-demographic characteristics of patients who initiate each treatment as opposed to other available maintenance treatments in COPD patients.

Study status

Planned

Research institutions and networks

Institutions

Aetion

Spain

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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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: 15/11/2019

Date of final study report
Planned: 30/04/2020

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

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The primary objectives of the study are to use US and UK data to describe the characteristics of COPD patients according to various demographic, lifestyle, clinical, and medication use at the time of diagnosis, at the time of initiation of first mantenance therapy and at the time of initiation of second maintenance therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

350000

Study design details

Outcomes

Patient characteristics, include various demographic, lifestyle, clinical, and medication characteristics will be reported at three points in time: 1) COPD claim confirming diagnosis date (Cohort Entry Date), 2) Date of initiation of first maintenance therapy (1st Treatment Index Date), overall and stratified by therapy category, 3)

Data analysis plan

• All covariates will be reported as mean (SD) and/or median (IQR) for continuous variables and counts and frequency (%) for categorical variables.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

CPRD

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