Preferences and consequences in therapy decision-making: tiotropium bromide plus olodaterol vs ICS-containing regimens in COPD patients in the Portuguese primary care setting: an observational, cross-sectional study (TIOLCOR Study)

First published: 16/06/2020

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48434

EU PAS number

EUPAS35841

Study ID

48434

DARWIN EU® study

No

Study countries

☐ Portugal

Study description

What are the differences between patients prescribed a new maintenance treatment for COPD with tiotropium/olodaterol (TIO/OLO) or ICS-containing regimens in terms of sociodemographic, anthropometric and clinical characteristics? - STUDY WAS CANCELLED -

Study status

Planned

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Primary lead investigator

Luis Pacheco

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/10/2020

Study start date
Planned: 30/06/2021

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:

Drug utilisation

Main study objective:

To describe and compare the sociodemographic, anthropometric and clinical characteristics of COPD patients at the time of prescription of a new maintenance regimen with TIO/OLO or an ICS-containing regimen (free or fixed dose triple combination ICS/LABA/LAMA, LABA+ICS, LAMA+ICS, ICS monotherapy or other) in the Portuguese primary care setting.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Name of medicine, other

Spiolto Respimat

Anatomical Therapeutic Chemical (ATC) code

(R01AD) Corticosteroids

Corticosteroids

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

300

Study design details

Outcomes

Demographic, anthropometric and clinical characteristics in the two study cohorts. Includes the number of patients for whom the new COPD treatment is in accordance with the GOLD 2019 Guideline recommendations, Patient symptomatology according to mMRC questionnaire and QoL according to EQ-5D-5L in the two study cohorts, Overall patient satisfaction with inhaler device according to a 5-point Likert scale and treatment satisfaction according to TSQM in the two study cohorts,

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Data analysis plan

All quantitative variables will be summarized using descriptive statistics. All qualitative variables will be summarized by absolute (n) and relative (%) frequencies. The statistical analysis will be performed through frequency tables for qualitative variables and tables with descriptive statistics for quantitative variables. A logistic regression will be used to explore the association between the dependent variable and independent variables of interest.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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