Characteristics of patients initiating Spiriva Respimat in Asthma in the UK: a cross-sectional study based on the Clinical Practice Research Datalink

First published: 12/10/2018

Last updated: 01/07/2021

Study Planned

Administrative details

EU PAS number

EUPAS25682

Study ID

25683

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study is a cross-sectional, non-interventional study based on existing data (NISed). The UK CPRD data will be used to assess thecharacteristics of asthma patients who were prescribed ICS/LABA FDC before the index date and who initiated Spiriva Respimat, or received a higher dose of ICS/LABA FDC, or initiated LTRA, or switched to a new ICS/LABA FDC in the UK during the study period (September 2014-December 2017) enabling to assess potential channeling of prescribing to different patient populations.

Study status

Planned

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Primary lead investigator

Jennifer Quint

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2018

Actual: 01/09/2018

Study start date

Planned: 23/10/2018

Date of final study report

Planned: 31/03/2019

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:

The main objective of the study is to describe the clinical and socio-demographic characteristics of asthma patients prior to the initiation of Spiriva Respimat for the treatment of Asthma within a general clinical population using the Clinical Practice Research Database (CPRD).

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TIOTROPIUM BROMIDE

Medical condition to be studied

Asthma

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

500

Study design details

Outcomes

The primary outcome is whether patient has Cardiac arrhythmias on the index date or in the year prior to the index date. The secondary outcome is whether patient has Cardiac failure on the index date or in the year prior to the index date.

Data analysis plan

Patient characteristics will be tabulated and summarized for all new users of Spiriva Respimat. In addition, patient characteristics will be tabulated for the

patients that initiated or switched to the other available treatments. Patient characteristics will be compared among patients who initiated Spiriva Respimat and patients in other treatment groups. Analyses will be conducted in unmatched cohorts and differences between Spiriva Restinmat and each of the other exposure groups will be assessed using absolute standardized differences (ASD),where an ASD of at least 10% will be considered a meaningful difference.

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