Taiwan Outcomes and Real-world Treatment Options for Chronic Obstructive Pulmonary Disease (TOReTO)

First published: 12/06/2019

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Study Planned

Administrative details

EU PAS number

EUPAS30087

Study ID

30088

DARWIN EU® study

No

Study countries

☐ Taiwan

Study description

The primary objective is to understand the occurrence of COPD exacerbations in patients treated with LABA/LAMA in the routine clinical practice in Taiwan.The secondary objectives are to realize the clinical characteristics and prescription patterns for the COPD population in Taiwan.

Study status

Planned

Research institutions and networks

Institutions

Linkou Chang Gung Memorial Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ying-Huang Tsai

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/07/2019

Study start date
Planned: 01/08/2019

Data analysis start date
Planned: 31/12/2019

Date of final study report
Planned: 29/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

TOReTO final protocol.pdf(907.23 KB)

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:

Effectiveness study (incl. comparative)

Main study objective:

The primary objective is to understand the occurrence of COPD exacerbations in patients treated with LABA/LAMA in the routine clinical practice in Taiwan.The secondary objectives are to realize the clinical characteristics and prescription patterns for the COPD population in Taiwan.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AL07) formoterol and glycopyrronium bromide

formoterol and glycopyrronium bromide

(R03AL06) olodaterol and tiotropium bromide

olodaterol and tiotropium bromide

(R03AL02) salbutamol and ipratropium bromide

salbutamol and ipratropium bromide

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

1800

Study design details

Outcomes

• Time to the first moderate or severe COPD exacerbation, • Annualized rate of mild/moderate/severe exacerbation• Time/reason (e.g. severe airflow limitation, diagnosis of asthma, worsening exacerbation) from LABA/LAMA escalating to LABA/LAMA/ICS or from LAMA to dual therapy• Percentage of patients receiving LABA/LAMA switched to triple therapy or LAMA switched to dual therapy

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Data analysis plan

A Data Validation Plan (DVP) will be prepared to describe the processes for data validation.The data abstracted from the medical chart will be described with number, mean, standard deviation (SD), range, and 95% confidence intervals (95% CI) for continuous variables, and frequencies and percentages for categorical variables.

Documents

Study, other information

TOReTO site list.pdf(94.93 KB)

Data management

Data sources

Data sources (types)

Drug dispensing/prescription data

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