Exacerbation Risk and Health Care Resource use among patients with asthma using ICS+Tiotropium versus ICS/LABA

First published: 10/11/2021

Last updated: 16/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS44101

Study ID

44102

DARWIN EU® study

No

Study countries

United States

Study description

To conduct a comparative analysis of patients using Tiotropium in combination with Inhaled Corticosteroids (ICS) versus those that use LABA medication in combination with ICS.

Study status

Finalised

Research institutions and networks

Institutions

eMAX Health

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Samir Khoury samir.khoury@boehringer-ingelheim.com

Study contact

samir.khoury@boehringer-ingelheim.com

Primary lead investigator

Samir Khoury

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 04/08/2020

Actual: 04/08/2020

Study start date
Planned: 01/10/2015

Actual: 14/05/2021

Data analysis start date
Planned: 14/05/2021

Actual: 14/05/2021

Date of final study report
Planned: 23/11/2021

Actual: 09/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer-ingelheim

Study protocol

0205-0547_CTP_final-rule_redacted.pdf (330.02 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To conduct a comparative analysis of patients using Tiotropium in combination with Inhaled Corticosteroids (ICS) versus those that use LABA medication in combination with ICS.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SPIRIVA RESPIMAT

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

TIOTROPIUM

Anatomical Therapeutic Chemical (ATC) code

(R03BB04) tiotropium bromide

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)

Estimated number of subjects

2.000

Study design details

Outcomes

The primary endpoint measure is time to first severe exacerbation, ● Time to first moderate-or-severe exacerbation ● Proportion of patients with exacerbation ● Rate of exacerbation at 6 months and one year ● Proportions of patients with Health care resource utilization (HCRU). HCRU is defined as hospitalizations, emergency

---

Data analysis plan

Sample attrition at each step of the inclusion-exclusion criteria will be provided. We will develop the breakdown of the distribution of demographic, comorbidity, and baseline measures prior to and after the PSM (unmatched and matched cohorts). Significance of differences will be tested at $P<0.05$ for the matched cohort. Additionally, we will consider the use of standardized mean differences as noted above, in which SMD <0.1 indicates balance of baseline covariates. The primary endpoint measure is time to first severe exacerbation and severe exacerbation will be defined as a hospitalization or an ER visit with a primary

Documents

Abstract of study report

0205-0547_Synopsis.pdf (325.35 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 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