The effectiveness of Tiotropium Add-on therapy using a Real-world cohort of patients with Asthma (Tiotropium therapy in Asthma)

First published: 29/05/2019

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS29889

Study ID

30994

DARWIN EU® study

No

Study countries

☐ United States

Study description

To evaluate the effectiveness of add on therapy with Tiotropium Respimat® compared to increasing the dose of ICS in patients with a diagnosis of Asthma and on ICS/LABA therapy

Study status

Ongoing

Research institutions and networks

Institutions

eMAX Health

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Samir Khoury

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/06/2018

Actual: 08/06/2018

Study start date
Planned: 05/02/2019

Actual: 15/03/2019

Data analysis start date
Planned: 05/02/2019

Date of final study report
Planned: 31/08/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer-ingelheim Pharmaceuticals

Study protocol

BI Tio-Asthma protocol 03-13-2019_2.pdf (431.75 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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the effectiveness of add on therapy with Tiotropium Respimat® compared to increasing the dose of ICS in patients with a diagnosis of Asthma and on ICS/LABA therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Tiotropium Bromide

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

TIOTROPIUM

Medical condition to be studied

Asthma

Population studied

Age groups

- Adolescents (12 to < 18 years)

Estimated number of subjects

6300

Study design details

Outcomes

The primary outcome measure is time to first exacerbation per person, Secondary endpoints will include,Rate of exacerbation,Health Care Resource Utilization (HCRU)HCRU is defined as frequency of hospitalizations, ER visits, and outpatient visits during follow-up, all-cause and asthma related, and the associated costs (medical and pharmacy).

Data analysis plan

For the primary endpoints analysis, we will calculate the time to first exacerbation per patient and compare it between the two groups (Tio vs.

NonTio). For secondary endpoint analyses we will compare the rate of exacerbation, proportion of patients with exacerbations after 6 months and one year (based on Kaplan Meier estimates), HCRU and average cost during follow-up and compare them between the two groups (Tio vs. NonTio). We will calculate time to first biologic use during follow-up. The primary outcome of the study will be analyzed using Cox proportional hazard modelling. The secondary outcome of rate of exacerbation per patient will be analyzed using negative binomial regression.

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