# 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

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Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/30994

**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

**First published:** 01/02/2024

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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

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**Study start date**

Planned: 05/02/2019

Actual: 15/03/2019

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**Data analysis start date**

Planned: 05/02/2019

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**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

**Name of medicine, 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).

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**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

## 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