

# 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

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### Study ID

30994

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### DARWIN EU® study

No

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### Study countries

 United States

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### 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

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### 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

[samir.khoury@boehringer-ingelheim.com](mailto:samir.khoury@boehringer-ingelheim.com)

### 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

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## Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **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

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

TIOTROPIUM

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**Medical condition to be studied**

Asthma

## Population studied

**Age groups**

- Adolescents (12 to < 18 years)
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**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

### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No