# Effectiveness of Dymista® in patients with allergic rhinitis and asthma

**First published:** 13/08/2019

**Last updated:** 01/04/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS30940

**Study ID**

30941

**DARWIN EU® study**

No

**Study countries**

☐ United Kingdom

**Study description**

A pre-post historical cohort study evaluating the effectiveness of a novel combination therapy of antihistamine and intranasal corticosteroid (Dymista®) on asthma-related outcomes among patients with allergic rhinitis and asthma

multi-morbidity. The primary objective is to examine the effectiveness of Dymista® in terms of improving asthma control by comparing the number of acute respiratory events and other measures of asthma control in the year before and after initiation of Dymista®.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

**First published:** 06/10/2015

**Last updated:** 19/08/2024

**Institution** | **Educational Institution** | **Laboratory/Research/Testing facility** | **ENCePP partner**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

David Price

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 03/05/2019

Actual: 25/02/2019

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**Study start date**

Planned: 24/05/2019

Actual: 24/04/2019

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**Data analysis start date**

Planned: 24/05/2019

Actual: 24/04/2019

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**Date of final study report**

Planned: 23/08/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Mylan

## 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:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

**Main study objective:**

To examine the effectiveness of Dymista® in terms of improving asthma control by comparing the number of acute respiratory events and other measures of asthma control in the year before and after initiation of Dymista®.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Dymista

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**Anatomical Therapeutic Chemical (ATC) code**

(R01) NASAL PREPARATIONS

NASAL PREPARATIONS

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**Medical condition to be studied**

Asthma

Rhinitis allergic

## Population studied

**Short description of the study population**

Asthma patients, aged ≥12 years who initiated Dymista® for treatment of allergic rhinitis.

Patients with following criteria were included:

• Initiation of Dymista® (patients receive ≥1 prescription of Dymista® any time)

• Diagnosis of asthma ever: diagnostic read code ever following the Quality Outcomes Framework (QOF)

• Age ≥12 years at IPD;

• Active asthma, defined as ≥1 prescription for an inhaler (reliever or controller) in the year prior to and including IPD

• Continuous electronic medical data for ≥1 year prior to IPD

• ≥1 year of electronic medical data after IPD

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**Age groups**

- Adolescents (12 to < 18 years)
- 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)

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**Special population of interest**

Other

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**Special population of interest, other**

Asthma patients

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**Estimated number of subjects**

1188

## Study design details

**Outcomes**

Change in the number of acute respiratory events was defined as occurrence of any of the following events separately or together (occurrences within 14 days of each other were considered to belong to the same event). Change in the number of asthma exacerbations, GINA treatment step, asthma control (Risk Domain Asthma Control and Overall Asthma Control), average daily dose of SABA and control of asthma symptoms (GINA level control)

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**Data analysis plan**

Patients initiating Dymista® were identified. The number of acute respiratory events in the baseline year and outcome year were determined. The effectiveness of Dymista® on the number of acute respiratory events in the baseline year was compared with the number of events in the outcome year by using the Wilcoxon signed rank test (for paired data). The results were reported as the proportion of patients who improved, worsened and stayed stable in the number of, for instance, acute respiratory events.

# 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 source(s)**

Optimum Patient Care Research Database

**Data sources (types)**

Electronic healthcare records (EHR)

## 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