

# Eosinophilic asthma phenotypes and associated clinical outcomes

**First published:** 24/09/2019

**Last updated:** 02/07/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS31500

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### Study ID

31501


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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

We will conduct a historical database study to characterise risk in regard to eosinophilic and non-eosinophilic asthma phenotypes and associated characteristics. The study will include asthma patients, aged  $\geq 13$  years, who

had controller or reliever inhaler therapy prescribed in the most recent 12 months of electronic medical records (EMR) extracted from UK general practices delivering data to Optimum Patient Care Research Database (OPCRD) and Clinical Practice Research Datalink (CPRD). Patients need to have at least one blood eosinophil recorded after first asthma diagnosis. To better understand the heterogeneity of asthma two different strategies will be applied to identify phenotypes. Patients will be classified into different grades of likelihood of eosinophilic asthma based on blood eosinophil counts and clinical features. In addition, unsupervised cluster analyses will be performed to identify different phenotypes of asthma which will be compared with the predefined phenotypes. Demographics, diagnosed comorbidities, clinical characteristics, such as asthma severity and control and health care resource utilisation (HCRU) will be described and compared for different phenotypes (both predefined and identified clusters) over the last 12 months of EMR data. Among patients who had multiple blood eosinophil counts available, those with persistently high blood eosinophil counts will be compared with patients without or with intermittently high counts using a separate design. These groups will be characterized and compared in a baseline period and clinical outcomes & HCRU will be compared in a follow-up year, using the most recent eosinophil count as the index date.

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## **Study status**

Planned

## **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

David Price [marjan@opri.sg](mailto:marjan@opri.sg)

**Study contact**

[marjan@opri.sg](mailto:marjan@opri.sg)

### Primary lead investigator

David Price

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 03/06/2019

Actual: 27/06/2019

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**Study start date**

Planned: 15/10/2019

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**Data analysis start date**

Planned: 01/11/2019

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**Date of interim report, if expected**

Planned: 13/12/2019

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**Date of final study report**

Planned: 01/04/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To describe and compare characteristics, such as asthma severity and control and health care resource utilisation (HCRU) of patients with predefined grades of likelihood of the eosinophilic asthma phenotype in a recent population of real-life patients with active asthma and to compare these phenotypes with phenotypes identified from unsupervised cluster analyses

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

**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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### **Estimated number of subjects**

400000

## Study design details

### **Data analysis plan**

Demographics, diagnosed comorbidities, clinical characteristics, such as asthma severity and control and HCRU of asthma patients will be described for the total population and for different phenotypes separately. Analyses will be repeated in the subpopulation of patients who were on the register of patients with active asthma that general practitioners maintain in the UK within the Quality and Outcomes Framework (QOF). Within this subpopulation characteristics will be also be compared between patients with and without severe asthma (as questionnaire data will be available for more detailed assessment of asthma control). K-means clustering will be used to identify clusters of eosinophilic phenotypes using all available characteristics. Patient groups distinguished based on the longitudinal pattern of eosinophil counts will be characterised and compared in a baseline period prior to the last eosinophil count and future clinical outcomes & HCRU will be compared in a follow-up year.

## Documents

## Study publications

Price DB, Rigazio A, Campbell JD, Bleecker ER, Corrigan CJ, Thomas M, Wenzel SE...

Kerkhof M, Tran TN, Soriano JB, Golam S, Gibson D, Hillyer EV, Price DB. Health...

Price DB, Bosnic-Anticevich S, Pavord ID, Roche N, Halpin DM, Bjermer L, Usmani...

Kerkhof M, Tran TN, van den Berge M, Brusselle GG, Gopalan G, Jones RC, Kocks J...

Price D, Wilson AM, Chisholm A, Rigazio A, Burden A, Thomas M, King C. Predicti...

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## 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)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

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### Data sources (types)

## 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