

# Benefits of high dose ICS in patients with asthma and high blood eosinophil counts

**First published:** 18/10/2016

**Last updated:** 21/02/2024

Study

Planned

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/15870>

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### **EU PAS number**

EUPAS15869

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### **Study ID**

15870

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### **DARWIN EU® study**

No

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### **Study countries**

United Kingdom

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## **Study description**

A previous study conducted by the Observational and Pragmatic Research Institute (OPRI) found that patients with asthma and high blood eosinophil counts experience more severe exacerbations and have poorer asthma control. The results suggest that this subpopulation of patients with asthma does not respond well to guideline-recommended therapy. There is no evidence available that a step-up to high dose ICS would be effective in preventing asthma attacks in these patients. Nevertheless, high ICS doses are frequently prescribed in real-life, exposing patients to the risk of adverse effects. The objective is to study the effectiveness of initiating patients with high blood eosinophil counts on high dose ICS to reduce exacerbation risk and to achieve asthma control. Patients with asthma and high blood eosinophil counts who step-up to high dose ICS will be extracted from the Clinical Practice Research Datalink or the Optimum Patient Care Research Database (date is index date (ID)). Patients who step-up from medium to high dose ICS will be matched to and compared with control patients on stable medium dose treatment during follow-up. The ID of control patients will be chosen at exactly the same number of days after the date of blood eosinophil count recording as the matched step-up patient. Patients who step up from low to high dose ICS will be matched to and compared with patients who step up from low to medium dose ICS. Patients will be matched on the following characteristics assessed in the year prior to ID: timing and value of eosinophil count, number of exacerbations, ICS drug and dose, propensity score of high dose ICS assignment. Survival and negative binomial regression analyses will be used to compare the rates of asthma exacerbations over 1 and 3 years of follow-up.

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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

**Study contact**

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

### Primary lead investigator

David Price

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 30/05/2016

Actual: 30/05/2016

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### **Study start date**

Planned: 09/09/2016

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### **Data analysis start date**

Planned: 17/10/2016

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### **Date of interim report, if expected**

Planned: 03/02/2017

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### **Date of final study report**

Planned: 31/03/2017

## 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:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

To study the effectiveness of initiating patients with high blood eosinophil counts on high ICS doses to reduce future exacerbation risk and to achieve asthma cont

## Study Design

**Non-interventional study design**

Cohort

## 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**

7200

## Study design details

### **Outcomes**

Number of severe asthma exacerbations, Acute oral corticosteroid courses for respiratory conditions  
Hospitalizations for asthma exacerbation  
Acute respiratory events  
Excessive use of Short-acting  $\beta$ 2-agonists (SABA)

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### **Data analysis plan**

Conditional Cox regression will be performed with time to the first event during stable ICS treatment as the outcome variable to estimate HRs with 95% CI.

Right censoring will be applied when a change in ICS prescriptions is observed during follow up. Conditional negative binomial regression / logistic regression with the number of events per time periods of one and three years will be performed to estimate RRs / ORs with 95% CI for patients with a continuous follow up time without a change in ICS prescription for these time periods.

## Data management

### Data sources

**Data source(s)**

Clinical Practice Research Datalink  
Optimum Patient Care Research Database

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**Data sources (types)**

[Other](#)

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**Data sources (types), other**

Prospective patient-based data collection

## 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