

# The role of adherence to inhaled corticosteroids in the relationship between blood eosinophilia and asthma control

**First published:** 03/11/2015

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11512

---

### Study ID

26263

---

### DARWIN EU® study

No

---

### Study countries

United Kingdom

---

### Study description

Patients with asthma and  $>0.4 \times 10^9$  blood eosinophils/L are characterized by increased severe exacerbation rates, reduced odds of achieving asthma control and being at higher steps of the GINA guidelines (step 3-4), compared to patients with asthma and lower eosinophil counts ( $<0.4 \times 10^9$ /L). Alternative therapies that target raised eosinophil counts are being introduced to the market but there is some concern that these treatments will only work for patients with poor adherence to their asthma therapy. A recent RiRL study found that within the UK, a high proportion of patients at higher GINA steps appear to be adherent to therapy but remain uncontrolled in terms of exacerbations and symptoms. Therefore, there is a need to clarify whether there exists a population of patients with asthma who have persistent elevated blood eosinophil counts, persistent exacerbations and who are adherent to ICS.

## Study status

Finalised

## 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 david@opri.sg

Study contact

david@opri.sg

### Primary lead investigator

Bakhtiyor Khalikulov

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/03/2015

---

### Study start date

Actual: 30/03/2015

---

### Date of final study report

Planned: 30/12/2015

Actual: 30/12/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Teva

## 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:**

Disease epidemiology

**Data collection methods:**

**Main study objective:**

To investigate whether poor adherence to ICS therapy explains occurrence of exacerbations or poor asthma control in patients with raised blood eosinophil counts at steps 3 and 4 of the GINA guidelines.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

**Short description of the study population**

Asthma patients with raised blood eosinophil counts at steps 3 and 4 of the GINA guidelines.

---

**Age groups**

- 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)
- 

### **Special population of interest**

Other

---

### **Special population of interest, other**

Asthma patients

---

### **Estimated number of subjects**

7195

## Study design details

### **Outcomes**

Demographic and clinical characteristics of the patients with raised and normal eosinophil levels at steps 3 or 4 of the GINA guidelines. Patterns of adherence to the ICS treatment in the asthma patients with raised and normal blood eosinophil levels at steps 3 and 4 of the GINA guidelines

---

### **Data analysis plan**

Descriptive statistics of the demographic and clinical characteristics of the patients with raised and normal eosinophil levels at steps 3 or 4 of the GINA guidelines will be produced. The number (%) of patients with exacerbations (routine, patient-reported and combined variables) and the proportion of patients with controlled asthma (routine and patient-reported variables) will be calculated. Sensitivity analyses for patients with good treatment adherence (>80%), as well as for lower adherence levels ( $\leq 80\%$ ) using eosinophils recordings within one year from questionnaire collection and lower cut-off for eosinophil levels ( $>0.3 \times 10^9/L$  and  $\leq 0.3 \times 10^9/L$ ) will be performed. Statistically

significant results will be defined as  $p < 0.05$  and trends as  $0.05 \leq p < 0.10$ . Differences between groups will be evaluated through Chi-square or Mann-Whitney U tests, as appropriate. Intra-group differences will be evaluated through Chi-square test ( $p < 0.05$ ).

## 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 source(s), other

iHARP United Kingdom

---

### 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**

Unknown