

# Burden of severe uncontrolled eosinophilic asthma in the UK population

**First published:** 03/09/2015

**Last updated:** 22/02/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS10229

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### Study ID

12824


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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

Background/Rationale: Benralizumab is a monoclonal antibody against the Interleukine-5 receptor, currently undergoing phase 3 clinical trials for use in the treatment of asthma. This therapy is being developed by AstraZeneca.

Benralizumab will target patients with severe, uncontrolled eosinophilic asthma treated with the combination of a high dose of inhaled corticosteroids (ICS) with a long-acting beta2-agonist (LABA). There is a need to establish the proportion of patients with severe uncontrolled eosinophilic asthma among the total population of asthma patients who would be eligible to be treated with benralizumab and to describe their burden of illness and healthcare resource utilisation (HRU). Objectives: The first objective is to describe the distribution of asthma severity, control, treatment status and blood eosinophilia and to establish the proportion of patients with severe uncontrolled eosinophilic asthma among the total population of asthma patients. The second objective will be to assess the rate of exacerbations and HRU during a follow-up year among patients with severe uncontrolled eosinophilic asthma. Study design: Patients with active asthma will be selected from the Clinical Practice Research Datalink (CPRD) and the Optimum Patient Care Research Database (OPCRD). The distribution of asthma severity and control, treatment status, blood eosinophilia, other asthma determinants and their combinations will be described in a baseline year prior to the date of the last blood eosinophil count (index date). Analyses will be performed in patients with and without an overlapping diagnosis of COPD separately. The rate of exacerbations and HRU will be described in the year after the index date in patients with severe uncontrolled eosinophilic asthma, defined as patients with blood eosinophilia, treated with high-dose ICS+LABA, who had  $\geq 2$  exacerbations for asthma in the baseline year.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

# Observational & Pragmatic Research Institute Pte (OPRI)

 United Kingdom

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

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**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

## Contact details

### Study institution contact

Kerkhof Marjan [marjan@rirl.org](mailto:marjan@rirl.org)

**Study contact**

[marjan@rirl.org](mailto:marjan@rirl.org)

### Primary lead investigator

David Price

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 03/01/2014

Actual: 06/03/2015

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**Study start date**

Planned: 06/07/2015

Actual: 27/07/2015

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**Data analysis start date**

Planned: 26/08/2015

Actual: 15/10/2015

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**Date of interim report, if expected**

Planned: 25/09/2015

Actual: 11/02/2016

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**Date of final study report**

Planned: 15/04/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## Study protocol

[Study protocol burden of severe uncontrolled eosinophilic asthma Final 26082015.pdf](#) (680.93 KB)

[20160304 Study protocol burden of severe uncontrolled eosinophilic asthma.pdf](#) (798.41 KB)

## Regulatory

## Was the study required by a regulatory body?

No

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Disease epidemiology

#### **Main study objective:**

The main objective is to describe the size of the population of patients with severe uncontrolled eosinophilic asthma and their burden of disease and health care resource utilisation

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

## **Medical condition to be studied**

Asthma

## **Population studied**

### **Age groups**

- Children (2 to < 12 years)
  - 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**

200000

## **Study design details**

### **Outcomes**

Asthma exacerbations and Healthcare Resource Utilisation, Indirect costs of asthma exacerbations

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### **Data analysis plan**

A historical follow-up study will be performed among the UK population of patients with active asthma extracted from OPCR and CPRD at the last recorded blood eosinophil count (index date). The distribution of asthma severity and control, treatment status, blood eosinophilia, other asthma determinants and their combinations will be described in the baseline year prior to the index

date in the total population and stratified by four age groups and the presence of blood eosinophilia using three cut-off values. The rate of exacerbations and HRU will be described in the outcome year in patients with severe uncontrolled eosinophilic asthma, defined as patients with blood eosinophilia, treated with high dose ICS + LABA who had  $\geq 2$  exacerbations in the baseline year. All analyses are performed in patients with and without an overlapping diagnosis of COPD separately.

## 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

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### **Data source(s), other**

OPCRD United Kingdom

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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