

# Burden of disease in patients with COPD and high blood eosinophil counts (High eosinophils and COPD)

**First published:** 31/01/2017

**Last updated:** 23/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS17543

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### Study ID

17544

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### DARWIN EU® study

No

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### Study countries

☐ United Kingdom

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### Study description

Patients with COPD with high blood eosinophil counts (BEC) have an increased risk of exacerbations. This study aims to evaluate the role of high BEC measured during stable disease in the burden and costs of COPD in a broad real-life population of patients in the United Kingdom. An observational historical follow-up study will be performed using medical records data for patients (aged  $\geq 40$  years) with COPD, from the Optimum Patient Care Research Database (OPCRD) and the Clinical Practice Research Datalink (CPRD). The study has the following objectives:

1. To study the association between high BEC at the time of stable COPD (i.e., no recent exacerbation and stable treatment during the study period) and the prospective exacerbation rate in different subgroups of patients with COPD defined by treatment regimen and smoking habits and to study whether this association is also found in patients with good adherence to ICS.
2. To study whether patients admitted to hospital for COPD exacerbation are more likely to be re-admitted if their pre-admission BEC is high.
3. A. To estimate mean all-cause and COPD-related health care resource use (HRU) and associated costs in 4 subgroups of patients who are at risk of exacerbations (i.e. a history of  $\geq 2$  exacerbations or  $\geq 1$  exacerbation leading to hospitalisation in the past 12 months) while receiving treatment with triple therapy, where the 4 subgroups are defined by the presence or absence of high BEC and current smoking habits.
- B. to compare HRU and costs with those for the total population of patients with COPD who have BECs available.
4. To study whether the presence of high BEC is associated with greater all-cause and COPD-related costs in the subsequent year and to study which other easily accessible characteristics drive future costs in patients with COPD.

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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

**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: 01/08/2016

Actual: 01/08/2016

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**Study start date**

Planned: 15/09/2016

Actual: 17/11/2016

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**Data analysis start date**

Planned: 03/10/2016

Actual: 31/01/2017

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**Date of interim report, if expected**

Planned: 16/12/2016

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**Date of final study report**

Planned: 17/04/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## Study protocol

[161207\\_R03315\\_Non-intervention study protocol\\_Burden of eosinophilic COPD V3.1.pdf](#) (1.17 MB)

## 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:**

Disease epidemiology

**Main study objective:**

To study the role of high blood eosinophil counts in the burden and costs of COPD in a broad real-life population of patients in the UK

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## Medical condition to be studied

Chronic obstructive pulmonary disease

## Population studied

### 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)
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### Estimated number of subjects

40000

## Study design details

### Outcomes

COPD exacerbation rate for objective 1, COPD-related short-term rehospitalisation for objective 2, COPD-related HRU and costs for objectives 3&4,

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### Data analysis plan

Binomial regression will be performed to estimate the adjusted association between high BEC and COPD exacerbations for objective 1. Cox-regression will be performed to estimate the adjusted association between high BEC and rehospitalisation for objective 2. HRU and mean costs will be described for different subgroups of patients on triple therapy who are at risk of exacerbations for objective 3. A one- or two-step generalized linear model with

gamma distribution and log link will be used to perform regression analysis with total costs as the outcome variable for objective 4.

## 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.

#### Conflicts of interest of investigators

[170105\\_David Price\\_COI.pdf](#) (11.63 KB)

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## Data sources

#### Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

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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