

# Prevalence of COPD patients with signs of asthma according to Dutch GP guidelines

**First published:** 07/02/2019

**Last updated:** 18/03/2019

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/28945>

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### EU PAS number

EUPAS27806

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### Study ID

28945

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### DARWIN EU® study

No

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### Study countries

Netherlands

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## Study description

Aims to describe the prevalence of asthma characteristics, like history of asthma/atopy, symptom pattern or reversibility, in patients with a pulmonologist confirmed working diagnosis of COPD or ACO. The primary outcome of this study is the percentage of COPD and ACO patients with asthma characteristics and in addition to that, the percentage of COPD and ACO patients which have no, one, two and three or more asthma characteristics is examined. Additionally, the percentage of asthma characteristics in COPD/ACO patients who have a blood eosinophil count of  $\leq 150$  cells per  $\mu\text{L}$ , between 151-300 cells per  $\mu\text{L}$  or  $> 300$  per  $\mu\text{L}$  is examined.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### General Practitioners Research Institute (GPRI)

Netherlands

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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**

Janwillem Kocks

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 08/01/2019

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### **Study start date**

Planned: 08/02/2019

Actual: 08/02/2019

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

Planned: 01/06/2019

## Sources of funding

- Pharmaceutical company and other private sector
- Other

## More details on funding

## 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:**

Not applicable

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

Disease epidemiology

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

To describe the prevalence of asthma characteristics in patients with pulmonologists working diagnosis of Chronic Obstructive Pulmonary Disease or Asthma/COPD overlap.

## Study drug and medical condition

## **Medical condition to be studied**

Chronic obstructive pulmonary disease

Asthma-chronic obstructive pulmonary disease overlap syndrome

## 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**

4900

## Study design details

### **Outcomes**

The primary outcome is the percentage of COPD/ACO patients with asthma characteristics including history of asthma, symptom pattern, history of atopy, reversibility. Additionally, the percentage of COPD/ACO patients which have one, two and three or more asthma characteristics are examined. The percentage of COPD and ACO patients with an exacerbation in the last year and the percentage of COPD and ACO patients with positive respiratory IgE levels. Additionally, the percentage of asthma characteristics in COPD/ACO patients who have a blood eosinophil count of  $\leq 150$  cells per  $\mu\text{L}$ , between 150-300 cells per  $\mu\text{L}$  or  $\geq 300$  per  $\mu\text{L}$ .

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## Data analysis plan

Standard statistical techniques and methodologies will be used to present the results of the intended goals described earlier, using SPSS, version 25. Baseline characteristics will be shown as mean  $\pm$  standard deviation (SD) or, in case of non-normally distributed data, median and interquartile range (IQR). The proportions of the asthma characteristics will be depicted in percentages.

## Data management

### Data sources

#### 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