

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

First published: 07/02/2019

Last updated: 25/06/2025

Study

Ongoing

Administrative details

EU PAS number

EUPAS27806

Study ID

28945

DARWIN EU® study

No

Study countries

☐ Netherlands

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 ≤ 150 cells per μL , between 151-300 cells per μL or >300 per μL is examined.

Study status

Ongoing

Research institutions and networks

Institutions

General Practitioners Research Institute (GPRI)

☐ Netherlands

First published: 31/08/2022

Last updated: 31/08/2022

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

Study start date

Planned: 08/02/2019

Actual: 08/02/2019

Date of final study report

Planned: 01/06/2019

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline, General Practice Research Institute

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 type:

Non-interventional study

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 Design

Non-interventional study design

Cross-sectional

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)

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 ≤ 150 cells per μL , between 150-300 cells per μL or ≥ 300 per μL .

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No