# Treatable Traits in patients with Obstructive Lung Diseases in Dutch primary care

**First published:** 14/06/2023

**Last updated:** 05/12/2024

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/105402

**EU PAS number**

EUPAS105378

**Study ID**

105402

**DARWIN EU® study**

No

**Study countries**

☐ Netherlands

**Study description**

Clinical guidelines for the management of obstructive lung diseases recommend a stepwise approach for treatment of asthma and COPD, but there is increasing realisation that a more personalised approach targeting “treatable traits” may be effective in achieving better control of these heterogeneous diseases. The Dutch asthma/COPD service (AC-service) supports general practitioners by diagnosing and monitoring patients with obstructive lung disease in a standardised way. Data collected within this framework offer a unique opportunity to quantify the frequency and stability of treatable traits among patients with obstructive lung disease.

Objectives:

A. To estimate the prevalence of eight treatable traits and the amount of overlap between these traits in patients with obstructive lung disease in Dutch general practice

B. To study the stability of treatable traits and the effect of management advice on changes in traits and health status in patients with obstructive lung disease who were assessed at a follow-up visit in Dutch general practice

Study design: A database study will be performed using data collected for the Asthma/COPD (AC)-service from patients with obstructive lung disease between 2007 and 2022. The presence (or absence) of eight treatable traits will be assessed at the patient’s first attendance to the AC-service. The stability of treatable traits and the effect of management advice on this and on health status will be assessed in patients who were followed-up by the service.

Study population: Patients attending the AC-service who were ≥18 years of age at the first AC-service attendance with a (working) diagnosis of asthma, COPD or Asthma-COPD overlap (ACO).

Analyses will be performed in:

1. The total study population of patients with a (working) diagnosis of asthma, COPD or Asthma-COPD overlap (ACO).

2. (Mutual exclusive) subpopulations of patients with a (working) diagnosis of:

a) Asthma b) COPD c) Asthma-COPD overlap (ACO)

**Study status**

Finalised

# 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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**Primary lead investigator**

Marjan Kerkhof

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 27/01/2023

Actual: 27/01/2023

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**Study start date**
Planned: 27/01/2023

Actual: 01/02/2023

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**Date of final study report**
Planned: 14/01/2024

Actual: 31/10/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GSK

## 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

**Study type:**

Non-interventional study

**Scope of the study:**

Disease epidemiology

**Main study objective:**

To estimate the prevalence of eight treatable traits and the amount of overlap between these traits in patients with obstructive lung disease in Dutch general practice.

## Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Database

## Study drug and medical condition

**Medical condition to be studied**

Chronic obstructive pulmonary disease

Asthma

**Additional medical condition(s)**

Asthma COPD Overlap

## 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**

17000

## Study design details

**Outcomes**

Presence (and overlap) of the treatable traits in patients assessed for asthma and/or COPD at the AC-service for the first time: • Type 2 eosinophilic inflammation • Reversible airflow obstruction • Poor adherence to lung medication • Insufficient inhaler technique • Current smoking • Anxiety or depression • Physical inactivity • Obesity (BMI >=30 kg/m2) or underweight (BMI <18.5 kg/m2), Individual changes in treatable traits status from the first to the second assessment Individual changes in health status and exacerbation rates between the first and second assessment by management advice. Effect of a management advice given for a treatable trait on changes in health status and exacerbation rates at the next assessment (difference in ACQ/CCQ and rate ratios for exacerbations

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**Data analysis plan**

A list of potential confounders, including sex and age, will be constructed based on the information available in the dataset. For all analyses, confounding of effect sizes will be evaluated by testing whether the effect size changes with >=5% after inclusion of the variable into the model. Starting with the crude model, the bias potential (% change in the coefficient of the fixed effect under study) of each potential confounder will be assessed. After that, the confounders will be sorted by their bias potential in a descending order, and the bias will be assessed against the previous model. In case the bias is >=5%, the candidate confounder will be retained in the model.

# Data management

## Data sources

**Data source(s), other**

Asthma-COPD service Netherlands

**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