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

First published: 14/06/2023

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Study Finalised

Administrative details

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

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Institution | **Laboratory/Research/Testing facility** | **ENCePP partner**

Contact details

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Study 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

Study start date
Planned: 27/01/2023

Actual: 01/02/2023

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 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

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), 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