

# PRAXIS - A real world longitudinal study of asthma and COPD in primary and secondary care

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Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/45689>

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### EU PAS number

EUPAS45688

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### Study ID

45689

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### DARWIN EU® study

No

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### Study countries

Sweden

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## Study description

A longitudinal real-world study of patients with asthma and COPD in primary care and hospitals setting. The aim is to identify different clinical phenotypes and to study how health-related quality of life, disease control, exacerbations and mortality are affected by gender, treatment, multimorbidity and symptoms.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

[Björn Ställberg, associate professor.](#)

[Uppsala University](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

[Psychiatric Epidemiology \(Psychepi Sweden\), Örebro University](#)

Sweden

**First published:** 21/04/2020

**Last updated:** 20/08/2024

**Institution**

**Educational Institution**

## Karolinska Institutet

Sweden

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

**Educational Institution**

Uppsala University Uppsala, Sweden, Örebro  
University Örebro, Sweden, Karolinska Institutet  
Stockholm, Sweden

## Networks

PRAXIS research network

## Contact details

**Study institution contact**

Björn Ställberg

**Study contact**

[b.stallberg@telia.com](mailto:b.stallberg@telia.com)

### **Primary lead investigator**

Björn Ställberg

**Primary lead investigator**

## Study timelines

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

Actual: 30/08/2021

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### **Study start date**

Actual: 07/02/2022

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

Planned: 31/12/2026

## Sources of funding

- Other

## More details on funding

The Swedish Heart and Lung Association, the Swedish Asthma and Allergy Association, the Bror Hjerpstedts Foundation, Swedish Heart-Lung Foundation, Regional Research Council Mid Sweden

## 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 identify different clinical phenotypes in a longitudinal real-world study of patients with asthma and COPD in primary care and hospitals setting. To study how health-related quality of life, disease control, exacerbations and mortality are affected by gender, treatment, multimorbidity and symptoms.

## Study Design

### **Non-interventional study design**

Cohort

Cross-sectional

## Study drug and medical condition

### **Medical condition to be studied**

Asthma

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**

11556

## Study design details

### **Outcomes**

Exacerbations, mortality, quality of life (using MiniAQLQ, CCQ or EQ5-DL) and disease control (ACT, CAT or mMRC). Treatment use. Use and interpretation of spirometry. Comorbidity among patients with asthma and COPD compared to a gender and age-matched reference population.

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## Data analysis plan

Data processing is done in SPSS and STATA. Risk factors for primary outcome variables will be analyzed using various statistical methods such as logistic regression and Cox regression. For factors affecting health-related quality of life, multiple linear regression will be used. For data-driven cluster analysis, pam algorithm is used.

## Documents

### Study, other information

[Publication list from the PRAXIS study group.pdf](#)(40.81 KB)

## Data management

## ENCePP Seal

### Composition of steering group and observers

[Steering Group in the PRAXIS-study.pdf](#)(7.15 KB)

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## Data sources

### Data source(s), other

PRAXIS-study Sweden

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

Drug dispensing/prescription data  
Electronic healthcare records (EHR)  
Other

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**Data sources (types), other**

Prospective patient-based data collection

## 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