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

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## Administrative details

#### **EU PAS number**

EUPAS45688

#### **Study ID**

45689

#### **DARWIN EU® study**

No

#### **Study countries**

Sweden

## **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.

## Study status

Ongoing

## Research institutions and networks

## Institutions

Björn Ställberg, associate professor.

## Uppsala University

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Institution

# Psychiatric Epidemiology (Psychepi Sweden), Örebro University

Sweden

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

## Networks

**PRAXIS** research network

## Contact details

Study institution contact Björn Ställberg b.stallberg@telia.com b.stallberg@telia.com

Primary lead investigator Björn Ställberg Primary lead investigator

# Study timelines

Date when funding contract was signed Actual: 30/08/2021

Study start date Actual: 07/02/2022

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

## 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 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

# 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)

## 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.

#### 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**

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.

**Composition of steering group and observers** Steering Group in the PRAXIS-study.pdf(7.15 KB)

## Data sources

Data source(s), other PRAXIS-study Sweden

## Data sources (types)

Administrative healthcare records (e.g., claims) Disease registry Drug dispensing/prescription data Electronic healthcare records (EHR) Other

#### 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

#### **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

## Data characterisation conducted

No