

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>

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 institution 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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Institution

Educational Institution

ENCePP partner

Karolinska Institutet

Sweden

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Institution

Educational Institution

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

Networks

Contact details

Study institution contact

Björn Ställberg

Study contact

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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

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)

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

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 data (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