Onset of asthma in severe asthma patients (PATH)

First published: 15/04/2021

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS40583

Study ID

43405

DARWIN EU® study

No

Study countries

- [ ] Bulgaria
- [ ] Canada
- [ ] Greece
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Kuwait

☐ Spain

☐ United Kingdom

☐ United States

Study description

This study aim is to describe and compare the demographic and clinical features of early-onset vs late-onset asthma phenotypes in an international cohort of adult patients with severe asthma. The primary objectives are: ● To describe the distribution of age of asthma onset in the international severe asthma registry cohort ● To define and validate the most appropriate age cut-off to delineate age-of-onset groups ● To describe and compare the demographic and clinical characteristics of the early-onset vs late-onset asthma phenotypes in adult patients with severe asthma The secondary objective is to evaluate possible geographical differences in early-onset and late-onset asthma phenotypes in severe asthma population. Data will be sourced from the International Severe Asthma Registry (ISAR). Anonymized person-level data from 9 countries will be used for this analysis. ISAR has governance provided by the ISAR scientific steering committee, The Anonymous Data Ethics Protocols and Transparency (ADEPT) committee, an independent body of experts and regulators commissioned by the Respiratory Effectiveness Group (REG).

Study status

Ongoing

Research institutions and networks

Institutions

Optimum Patient Care (OPC)

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Not-for-profit

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network | ENCePP partner

Respiratory Effectiveness Group (REG)

Belgium

Denmark

France

Germany

Greece

Hungary

Italy

- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 07/07/2021

Last updated: 04/06/2024

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/05/2018

Actual: 19/05/2018

Study start date

Planned: 01/09/2019

Actual: 16/01/2020

Data analysis start date
Planned: 01/11/2019

Actual: 18/03/2021

Date of final study report
Planned: 01/12/2021

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The study aims to describe and compare the demographic and clinical features of early-onset vs late-onset asthma phenotypes in an international cohort of adult patients with severe asthma.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Asthma

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

2000

Study design details

Outcomes

The primary outcome is to describe the distribution of age of asthma onset in the international severe asthma cohort, define and validate the most appropriate age cut-off to delineate age-of-onset groups and to describe and compare the demographic and clinical characteristics of the early-onset vs late-onset asthma phenotypes in adult patients with severe asthma. The secondary outcome is to evaluate possible geographical differences in early-onset and late-onset asthma phenotypes in a severe asthma population.

Data analysis plan

To define age cut-off, the study will explore the potential cut-offs through various methods including ROC curve analysis and best fitted model (highest area under the curve). Baseline characteristics will be reported for early-onset and late-onset asthma groups with continuous variables summarised using descriptive statistics, the frequency and percentages of observed levels will be reported for categorical variables, and tables will be annotated with the total population size. Characteristics of groups will be compared via contingency

tables and group difference will be tested for statistical significance via chi-square tests for comparison of counts. Moreover, t-test or one-way analysis of variance (ANOVA) will be applied to compare means across groups. Demographic or clinical constructs will be compared between early-onset vs late-onset severe asthma phenotype groups.

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

OPCG-1823_PATH_EnCEPP_Advisory Project Group.pdf(90.17 KB)

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

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