ImPact of comoRbidity In Severe asthMa patients (PRISM)

First published: 10/11/2021

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS44024

Study ID

50613

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Denmark

- [ ] Greece
- [ ] India
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Spain
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study status

Planned

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

David Price dprice@opri.sg

Study contact

dprice@opri.sg

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/05/2021

Study start date

Planned: 10/05/2021

Data analysis start date

Planned: 01/11/2021

Date of final study report

Planned: 28/02/2023

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

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To understand the pattern of comorbidities in adults with severe asthma and investigate their association with asthma-related outcomes

Study Design

Non-interventional study design

Cohort

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

11000

Study design details

Outcomes

The prevalence of comorbidities will be described in patients with severe asthma. The impact of T2-related comorbidities on response to biologics will be assessed

---

Data analysis plan

1. Overall prevalence of history of individual comorbidities (ever/never) will be calculated over the timeframe covered by ISAR. In addition, the number of comorbidities will be calculated for each patient and prevalence of comorbidity counts computed (eg, prevalence of 0, 1, 2, and 3+ comorbid conditions). 2.The prevalence estimates will be compared between demographic and clinical features: - through chi-square tests for categorical variables, - through t-test comparisons or non-parametric Wilcoxon tests for continuous variables. 3.For patients initiating biologics, we will compare patients with at least one T2 comorbidity or without T2 comorbidity, and by individual T2 comorbidity types, with respect to four asthma-related outcomes measured the period 24 weeks to 1 year following the biologic initiation:exacerbation rate (risk ratios), asthma control (difference of proportions), lung function (difference of means or medians), cumulative OCS dose (difference of means or medians)

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

Project Steering Committee Member_PRISM.pdf (31.8 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