Patient characteristics, treatment patterns, clinical outcomes, and health care resource utilization in severe asthma subgroups: A retrospective analysis of the International Severe Asthma Registry (EVEREST)

First published: 05/10/2023

Last updated: 21/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS106967

Study ID

106968

DARWIN EU® study

No

Study countries

- ☐ Argentina
- ☐ Australia

- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Greece
- [ ] India
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Poland
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Spain
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study description

Asthma is a heterogeneous disease with a complex pathophysiology that presents with a wide range of clinical manifestations and treatment responses. Recent advances in treatment strategies for severe asthma include the development and release of targeted biologics for treatment. Eligibility for biologic treatment is based on clinical and pathobiological markers, including biomarkers such as immunoglobulin E (IgE), fractional exhaled nitric oxide (FeNO), and blood eosinophil count (BEC). Despite these advances in treatment, the clinical burden for severe asthma remains high. The primary goal of this analysis is to use data from the International Severe Asthma Registry (ISAR)

registry to describe characteristics and unmet needs for patients with subtypes of severe asthma, including patients who are ineligible for current biologic treatment (biologic-ineligible), patients who are biologic-eligible, patients who are biologic-eligible with and without biologic treatment, patients on biologic therapy with uncontrolled asthma, patients with multiple positive asthma-specific biomarkers, patients with low vs high blood eosinophils count (BEC), and patients with allergic asthma. As an exploratory objective, this study will also examine the variability of asthma-specific biomarkers over time.

Study status

Finalised

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: 21/05/2025

Network | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/08/2021

Actual: 05/08/2021

Study start date

Planned: 01/12/2017

Actual: 31/05/2022

Date of final study report

Planned: 31/10/2021

Actual: 31/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

Exploratory: To describe the real-world fluctuation of biomarkers (IgE, FeNO, BEC) over time among patients with severe asthma with and without biologic therapy. Both numerical and categorical changes will be assessed.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective analysis

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

The study population included patients with asthma identified from the international severe asthma registry (ISAR).

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)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

13000

Study design details

Data analysis plan

The analysis for the primary objective will be descriptive in nature. Descriptive statistics will be calculated for continuous and categorical variables accordingly. For variables measured on the interval or ratio scale, summary statistics produced will include: -Sample size (n) -Frequency and percentage of missing data -Mean -Standard deviation (SD) 95% confidence intervals (CI) -Range (minimum–maximum) -Median -Interquartile range (25th and 75th percentile) For categorical variables, the summary statistics will include: -Sample size (n) -

Count for each category, including a missing data category -Percentage of the total number of observations for each category, including a missing data category

Data management

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

Disease registry

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