Biomarker Relatability in the International Severe Asthma Registry (BRISAR)

First published: 24/07/2019

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS30430

Study ID

33344

DARWIN EU® study

No

Study countries

- Bulgaria
- Canada
- Greece
- Ireland
- Italy
- Japan

Korea, Republic of

Kuwait

Spain

United Kingdom

United States

Study description

This study aims to characterise an international severe asthma population based on their pattern of biomarkers, potentially helping clinicians to classify and understand these patients.Primary objectives of this study are to assess the degree of overlap across commonly used asthma biomarkers of Type 2 inflammation (IgE, serum eosinophils and FeNO) among a diverse international cohort of severe asthma patients, and to characterise and compare severe asthma patients positive for different combinations of asthma biomarkers.This cross-sectional study will include baseline data of patients at the point of enrolment in the International Severe Asthma Registry (ISAR). This is an international registry combining retrospective and prospective data from the United States, Canada, Greece, Italy, Ireland, South Korea, Bulgaria, Kuwait, the United Kingdom and Spain with common data points of collection agreed on by 27 asthma experts worldwide. De-identified individual patient data will be classified categorically according to baseline biomarker status for analysis of characteristics, including demographics, lung function, asthma control, exacerbations, quality of life, presence of comorbidities and asthma medications.

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

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: 01/04/2018

Actual: 30/04/2018

Study start date
Planned: 01/05/2019

Actual: 01/05/2019

Data analysis start date
Planned: 15/07/2019

Date of interim report, if expected
Planned: 01/10/2019

Date of final study report
Planned: 29/02/2020

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

To assess the degree of overlap across commonly used asthma biomarkers of Type 2 inflammation (IgE, serum eosinophils and FeNO) among a diverse international cohort of severe asthma patients.To characterise and compare severe asthma patients positive for different combinations of asthma biomarkers as continuous and dichotomous variables.

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

6.275

Study design details

Data analysis plan

Patients will be classified according to each of 3 biomarkers: IgE, blood eosinophils andFeNO. Univariate distributions for demographics and clinical characteristics will be described for each of the biomarker groups. Categorical variables will be compared using Chi-squared statistics with p-values and presented as mean ± standard deviation. Continuous variables will be compared between biomarker groups via the independent samples t-test with p-values.Data reduction methods will be used to validate the clusters according to biomarker group using biomarkers as continuous variables (IgE, FeNO and serum eosinophils) to identify unique clusters in the ISAR cohort according to biomarker group status.Cluster analysis will then be used to group patients and the baseline characteristics of each group will be described.

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.

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