The Characterization and Comparison of Eosinophilic and Non-eosinophilic Phenotypes of Severe Asthma

First published: 12/09/2019

Last updated: 26/02/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/32956

EU PAS number

EUPAS31355

Study ID

32956

DARWIN EU® study

No

Study countries

☐ Bulgaria

- [ ] Canada
- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

This cross-sectional study design is the first step to better understand and assess the presence of eosinophilic and non-eosinophilic asthma phenotypes using known constructs of severe asthma epidemiology. Firstly, most likely non-eosinophilic asthma patients will be identified followed by discerning eosinophilic asthma patients with most likely versus likely degrees of confidence. The characteristics of eosinophilic and non-eosinophilic phenotypes will be compared to a benchmark (published results from a similar study population). Data for this study will be sourced from the International Severe Asthma Registry (ISAR). Parallel analyses using a primary care observational database, the Optimum Patient Care Research Database (OPCRD), will be conducted for providing a benchmark for comparison.

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: 14/08/2024

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: 01/04/2018

Actual: 30/04/2018

Study start date

Planned: 31/08/2018

Actual: 15/10/2018

Data analysis start date
Planned: 01/03/2019

Actual: 15/03/2019

Date of final study report
Planned: 31/01/2020

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPCG

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 describe and compare the demographic and clinical features of eosinophilic and non-eosinophilic asthma phenotypes in a cohort of adult patients with severe asthmaTo investigate the unique clusters of asthma phenotypes in the international severe asthma registry

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)

Estimated number of subjects

5000

Study design details

Outcomes

Description and comparison of demographic and clinical features of the eosinophilic versus non-eosinophilic phenotypes of severe asthma, Unique clusters of severe asthma phenotypes in the international severe asthma registry (ISAR)

Data analysis plan

Firstly, most likely non-eosinophilic asthma patients will be identified followed by discerning eosinophilic asthma patients with most likely vs likely degree of confidence. Descriptive statistics will be provided for continuous and categorical variables accordingly. Summary statistics will be produced for variables measured on the interval or ratio scale, including sample size, mean and SD and categorical variables including range and the percentage by category. A benchmark for each descriptive statistic will be calculated using OPCRD data. Characteristics of groups will be compared via contingency tables and group difference will be tested for statistical significance. Data reduction methods will be used to validate the expected clusters of eosinophilic phenotype and/or to investigate the unique cluster present in the ISAR cohort. Univariate distributions for patient characteristics and clinical characteristics will be described for four identified phenotypes.

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

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