Demographic and Clinical Characteristics of Severe Asthma Patients Worldwide

First published: 03/10/2018

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS25489

Study ID

27888

DARWIN EU® study

No

Study countries

- Australia
- Italy
- Korea, Republic of
- United Kingdom
- United States

Study description

This study aims to inform the asthma scientific community of the demographic and clinical characteristics of severe asthma patients seen at severe asthma centres across the globe. This will help drive the next key research questions to be asked at the country, region, and international level.This is a cross-sectional study to describe the severe asthma population, utilising data from the International Severe Asthma Registry (ISAR) to descriptively illustrate differences and similarities of demographic and clinical attributes of severe asthma patients globally. The study will include adult severe asthma patients receiving treatment according to the Global Initiative of Asthma (GINA) Step 5 or uncontrolled on GINA Step 4. Descriptive statistics will be summarized for demographic factors and clinical characteristics, including medical history, healthcare resource utilisation, blood test measurements, fractional exhaled nitric oxide (FeNO) test, comorbidities and medication use categories.

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: 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: 01/05/2017

Actual: 15/05/2017

Study start date

Planned: 01/11/2017

Actual: 16/04/2018

Date of interim report, if expected

Planned: 15/10/2018

Date of final study report

Planned: 31/12/2018

Actual: 31/01/2019

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

Study protocol

ISAR_global reseach topic protocol 2017 20180905 v0.4.pdf (350.75 KB)

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:

The primary objective of this study is to describe the global severe asthma population using aggregate demographic and clinical measures such as healthcare resource utilisation, blood test measurements, comorbidities, etc.The secondary objective is to descriptively compare the distribution of demographic and clinical attributes of severe asthma patients across sub-populations (regions/countries)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Historical study describing the baseline data of a cohort of severe asthma patients

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Severe asthma patients aged 18 years or older who received treatment according to GINA step 5 ot uncontrolled at Step 4. Uncontrolled is defined as having severe asthma symptoms or frequent exacerbations.

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

4.990

Study design details

Outcomes

Demographic and clinical characteristics of the global severe asthma population, Descriptive comparison of baseline and clinical characteristics of severe asthma population across countries

Data analysis plan

Descriptive statistics will be computed for all demographics and clinical variables for the patient population as categorical variables, and count and percentage of non-missing observations will be reported for each category.Country or region (group) comparison will be examined with contingency tables. Frequencies and 95% confidence intervals will be shown for each characteristic and group difference will be tested for statistical significance via chi-square test for comparison of counts. Statistical significance will be defined as $p < 0.05$.

Documents

Study results

ISAR global report 2017_final_updated_24.01.2019_ENCePP.pdf (1.35 MB)

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

Unknown