Demographic and Clinical Characteristics of Severe Asthma Patients Worldwide

First published: 03/10/2018
Last updated: 01/04/2024

Study Finalised

Administrative details

Contact details

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Primary lead investigator

David Price

Primary lead investigator

PURI

https://redirect.ema.europa.eu/resource/27888

EU PAS number

EUPAS25489

Study ID

27888

DARWIN EU® study

No

Study countries
Australia
Italy
Korea, Republic of
United Kingdom
United States
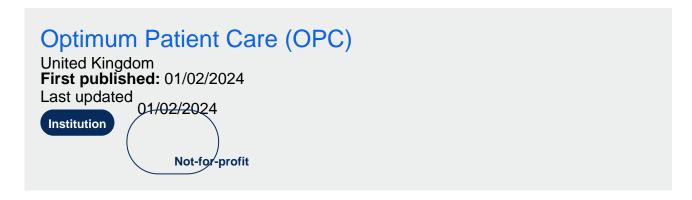

Study description
This study aims to inform the asthma scientific community of the demographic and clinical characteristics of severe asthma patients seen at severe asthma centres across the globe. This will help drive the next key research questions to be asked at the country, region, and international 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 institution 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 08/08/2023

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 08/07/2021

Network **ENCePP partner**

Study timelines

Date when funding contract was signed
Planned:
01/05/2017
Actual:
15/05/2017

Data collection
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 data collection

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 demogr

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
4990

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

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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

Results tables
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