Redefining severe asthma to high-risk asthma: Analysis of real-world data to investigate patients who are at high risk of exacerbations, worsening of symptoms, and a loss of asthma control over time.

First published: 17/07/2023

Last updated: 21/02/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105928

EU PAS number

EUPAS105920

Study ID

105928

DARWIN EU® study

No

Study countries

United Kingdom

Study description

To investigate patients with asthma to determine what characteristics, co-morbidities, treatments, and other clinical characteristics are associated with higher risk of exacerbations, worsening of symptoms and loss of asthma control.

Study status

Planned

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution **Educational Institution** **Laboratory/Research/Testing facility**

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: 31/07/2023

Study start date
Planned: 31/07/2023

Data analysis start date
Planned: 14/08/2023

Date of final study report
Planned: 06/11/2023

Sources of funding

- Other

More details on funding

OPRI

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

To investigate patients with asthma to determine what characteristics, co-morbidities, treatments, and other clinical characteristics are associated with higher risk of exacerbations, worsening of symptoms and loss of asthma

control.

Study Design

Non-interventional study design

Cohort

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

2000000

Study design details

Outcomes

Change in patients' asthma symptoms measured by changes in patients' treatments, clinical markers, and frequency and severity of exacerbations. These will be associated to patient's characteristics, and comorbidities to determine patients that are at high risk of worsening asthma outcomes.

Data analysis plan

Patient's characteristics will be measured at initial asthma diagnosis (ID) and over time and will include, but not be limited to, patient characteristics, clinical measures at baseline and over time, asthma treatments, and comorbidities. Statistical analysis for the baseline variables for each of the OCS prescribing categories will be descriptive in nature. They will provide the absolute and relative number of subjects, mean, median, standard deviation (SD), and interquartile range (IQG) for continuous variables for the baseline variables. Perform predictive analysis on variables thought to be predictive of a worsening of asthma symptoms/increase in exacerbations. Incident rate ratios for exacerbations will be calculated by baseline population types. Missing data for BMI, smoking status and PEF % predicted will be imputed using multiple imputation techniques.

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

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