PATTERNS OF CLINICAL MANAGEMENT OF ASTHMATIC PATIENTS WITH EXACERBATIONS IN THE REAL-WORLD SETTING IN THE NATIONAL HEALTH SYSTEM

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Study Finalised

Administrative details

EU PAS number

EUPAS28551

Study ID

28552

DARWIN EU® study

No

Study countries

Spain

Study description

Despite the availability of effective treatments, numerous studies (also in Spain) have shown a high prevalence of sub-optimal control of asthma that is associated with an increase of exacerbations which, when they are moderate to severe, entail significant use of expensive health care resources. The negative effects of inadequate control of asthma include increased risk of exacerbations, more emergency room visits and hospitalizations and higher mortality rate. In fact, patients with uncontrolled asthma have higher costs and lower quality of life than patients who are controlled.In our context, the evidence available in the real-world setting about how these patients are and how they are managed in the spanish National Health System is very scarce. There are few population-based studies, and in most cases, there are only small cohorts that may suffer from biases of representativeness and observation, which limits their extrapolation to all asthmatic patients with exacerbations. In the Valencian Community there is the ability to carry out studies in the real-world setting thanks to the availability of different population-based clinical and management information systems, that can be linked to individual patients through a unique identifier.The current project focuses on describing the characteristics of asthmatic patients with exacerbations, pharmacotherapeutic management patterns after exacerbation, and the use of associated health care resources, from a real-world population cohort that includes the entire population of asthma patients with exacerbations of the Valencian Community.

Study status

Finalised

Research institutions and networks

Institutions

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

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Institution

Contact details

Study institution contact

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Primary lead investigator

Salvador Peiró

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/12/2018

Actual: 10/12/2018

Study start date

Planned: 01/05/2019

Actual: 27/02/2019

Data analysis start date

Planned: 02/09/2019

Actual: 27/02/2019

Date of final study report

Planned: 31/12/2019

Actual: 27/02/2019

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

GSK, FISABIO

Study protocol

20190211 01_1 ASTHMA_V1_0 PROTOCOL.pdf (1.36 MB)

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

Other

Study topic, other:

Disease/Epidemiology Study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the incidence and prevalence of asthma in the region of Valencia and to describe the characteristics of asthmatic patients with exacerbations, the pharmacotherapeutic management patterns after exacerbation, and the

use of associated health care resources, from a real-world population cohort that includes the entire population of asthma patients with exacerbaiton of the region.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Asthmatic crisis

Population studied

Short description of the study population

Asthma patients with exacerbations of the Valencian Community.

Inclusion critera:

1. General cohort of asthmatic patients. All persons 18 and over years of age (fulfilled between 2010 and 2018) were included who have at least one diagnosis of

asthma (ICD9MC: 493.xx, ICD10MC: J45) in any of the information systems used (SIA, MBDS, SIUH).

2. Exacerbation cohort: Cases were selected from the general cohort who have

at least one exacerbation episode between 2015 and 2016, excluding those older than 55 years on the date of the index exacerbation. The first episode of exacerbation in this period were considered the index episode and will define the onset of the follow-up period

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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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

15.000

Study design details

Outcomes

To describe the characteristics of asthmatic patients with exacerbations (socio-demographic characteristics, comorbidities, clinical risk.To describe the pharmacotherapeutic management of these patients following the index exacerbation.To describe the use of healthcare resources, the deaths and the loss of productivity (days of sick leave) in the year following the index

exacerbation. To describe the incidence of asthma in the reion of Valencian over the study period (cohort 2010 - 2018).To describe the incidence of asthma exacerbations, deaths and days of sick leave in the Valencian Community over the study period (2015 to 2017).To analyse the association between baseline risk (history of pattern of exacerbation and therapeutic step) and the risk of future exacerbations.

Data analysis plan

1. Description of baseline characteristics of patients with asthmatic exacerbation, including history of exacerbation and treatment step at baseline (using GPC-established steps for asthma management in adults).2. Description of short-term (month after index exacerbation) and long term-patterns of pharmacotherapeutic management (treatment step in the 12 months after index exacerbation). 3. Description of intensity in the use of SABA as rescue medication in the 12 months after the date index.4. Description of the use of health resources, death and sick leaves in the year following the index exacerbation.5. Describe the incidence of asthma and of asthma exacerbations in the region. For the calculation of crude exacerbation rates, a Poisson regression model with adjustment for the estimated overdispersion parameter will be used.6. Analyse the association between baseline risk (history of exacerbation and step of treatment) using Cox models and represented by Kaplan-Meier graphs.

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.

Signed code of conduct

20190211 03 ASTHMA_COMPROMIS INVESTIGADORS.pdf (690.64 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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

Unknown