Non-interventional, cross-sectional, multicenter study to describe the exacerbations profile of COPD patients Treated with ICS in a real-life primary care population in Spain. OPTI Study

First published: 05/03/2018

Last updated: 15/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS22940

Study ID

39847

DARWIN EU® study

No

Study countries

Spain

Study description

This study has been designed in order to describe the COPD patient profile of patients treated with or without ICS in primary care, in Spain. Primary objective: To describe the patient profile for patients treated with ICS at the time of study visit. Secondary objectives: a) To describe the patient profile for patients not treated with ICS at the time of study visit. b) To assess the proportion and the number (count) of patients with COPD treated with ICS at the time of study visit with or without moderate-to-severe exacerbations, both in the previous 1 year and previous 2 years before the study visit. c) To assess the proportion and the number (count) of patients with COPD not treated with ICS at the time of study visit with or without moderate-to-severe exacerbations, both in the previous 1 year and previous 2 years before the study visit. d) Use of rescue medication. e) Adherence to treatment recommendations according GesEPOC guidelines. f) To describe ICS-related adverse events. The design of the study impose an only visit to be performed that will coincide with one of those performed by the patients as part of routine follow-up of their disease, without interfering with usual clinical practice of the investigator. Approximately 1,000 patients with COPD are planned to be included in the study in 200 sites. To minimize selection bias at the patient level, the first 5 consecutive patients from each site who met all inclusion criteria and none of the exclusion criteria will be enrolled during one year. Data will be obtained from patient medical records and during the study visit. Most of data will be available in the charts but as a routine clinical practice, some data could be missing. Data will be collected through an eCRF which will include all the study variables. CAT – COPD Assessment Test will be filled in by the patient during the study visit and data will be entered electronically into the CRF system by the Investigator.

Study status

Finalised

Research institutions and networks

Institutions

University Hospital Vall d’Hebron (HUVH)

Spain

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Multiple centres: 200 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marc Miravitlles

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 09/02/2018

Actual: 09/02/2018

Study start date
Planned: 18/07/2018

Actual: 21/09/2018

Data analysis start date
Planned: 04/05/2020

Actual: 02/06/2020

Date of final study report
Planned: 18/01/2021

Actual: 09/02/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim España, S.A

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:

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To describe the patient profile for patients treated with ICS at the time of study visit.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Chronic obstructive pulmonary disease (COPD) patients treated with or without ICS in primary care, in Spain.

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

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

1000

Study design details

Outcomes

The primary outcome is to describe the proportion of patients currently on ICS who did not have moderate/severe exacerbation in the year prior to the study visit. Some of the secondary objectives are:- To describe the patient profile for patients not treated with ICS at the time of study visit- To assess the proportion and the number (count) of patients with COPD treated with ICS at the time of study visit with or without moderate-to-severe exacerbations, both in the previous 1 year and previous 2 years before the study visit.

Data analysis plan

The primary outcome is to describe the proportion of patients currently on ICS who did not have moderate/severe exacerbation in theyear prior to the study visit.Sub-group analysis in the group of patients treated with ICS may be considered according ICS long term use and ICS only for short courses.Since the study is descriptive, the variables included in the study objectives will be summarized overall and by factors of interest. All results will be summarized with measures of central tendency (mean and median), variability/dispersion (standard deviation and interquartile ranges), absolute and relative frequencies, and ranges.The analysis population will consist of all eligible patients (i.e. all patients fulfilling all inclusion criteria and no exclusion criteria). If patients have missing values for an outcome, those patients will be excluded for that outcome’s analysis. Missing data will not be imputed.

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.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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