

Exacerbation history in COPD patients prior to diagnosis and subsequent treatment and outcomes

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Study

Planned

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/105870>

EU PAS number

EUPAS105737

Study ID

105870

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This is a historical cohort study of patients in the year prior to and the year following the patients initial COPD diagnosis. The index date will be the patients first COPD diagnosis. Patients will be followed for one year prior and one year following their initial COPD diagnosis.

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

David Price

Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/06/2023

Study start date

Planned: 10/07/2023

Data analysis start date

Planned: 24/07/2023

Date of interim report, if expected

Planned: 25/08/2023

Date of final study report

Planned: 29/09/2023

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

Other study registration identification numbers and links

OPRI 2306

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To describe the number of exacerbations in the year prior to first COPD diagnosis, the patient's characteristics at time of diagnosis, and the treatments and number of exacerbations by severity in the year following diagnosis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

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

70000

Study design details

Outcomes

The number of exacerbations following initial COPD diagnosis by severity, frequency and initial treatment

Data analysis plan

Incident rate ratios will be calculated for any exacerbation/severe exacerbations and initial treatment following the index date.

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