Prevalence and healthcare utilization of eosinophilic chronic obstructive pulmonary disease in the UK – an observational data linkage study

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000783

Study ID

1000000783

DARWIN EU® study

No

Study countries

United Kingdom

Study description

We will conduct a study to determine the number and demographic characteristics of patients with eosinophilic Chronic obstructive pulmonary disease (COPD) in the UK broken down by eligibility for biologic therapies.

Study status

Ongoing

Research institutions and networks

Institutions

Queen's University Belfast

First published: 01/02/2024

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Institution | Educational Institution

Networks

HDRUK

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Actual: 23/05/2023

Study start date
Actual: 01/04/2025

Data analysis start date
Actual: 01/06/2025

Date of final study report
Planned: 01/04/2026

Sources of funding

- Non-EU institutional research programme

More details on funding

Health Data Research UK (HDR-UK, https://www.hdruk.ac.uk/)

Study protocol

eosinophilic COPD study plan.pdf (293.18 KB)

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

ADEPT 0825

https://www.regresearchnetwork.org/

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

We will identify all patients with COPD in OPCRD. Within that population, we will identify (a) those with active COPD; (b) those diagnosed eosinophilic; (c) with an asthma comorbidity; (d) on triple therapy and (e) with >1 and >2 exacerbations. Cohorts will be followed up in 2024 for health outcomes

Main study objective:

To estimate the number and proportion of patients with COPD stratified by eosinophil count, asthma comorbidity, exacerbations and current therapy. To calculate the annual rate of different health outcomes in patients who are potentially eligible for biologic therapy and patients who are not .

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

The study population are adult patients registered with Optimum Patient Care Research Database (OPCRD) with a diagnostic code indicative of COPD.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

Inclusion criteria are all adult patients registered within OPCRD (approximately 10% of the general population in the UK) with a diagnostic code for COPD. Patients need to be continuously registered between 1.1.2021 and 1.1.2024. and have valid information available for age and sex.

Outcomes

(1) Number and proportion in the different cohorts; (2) risk factors associated with membership to the different cohorts (odds ratios); (3) hazards and hazard-ratios of disease progression; (4) number of exacerbations (measure for disease progression)

Data analysis plan

Logistic regression for the risk factors; full-parametric survival analysis for the hazards of disease progression; negative binomial regression for the number of exacerbations. Data management and analysis in MS-SQL Server and R, respectively. All classification will be based on the linked electronic health records, using published code lists and code lists generated by OPCRD.

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 source(s)

Optimum Patient Care Research Database

Data sources (types)

Drug prescriptions

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