

THE RELIABILITY AND UTILITY OF BLOOD EOSINOPHILS AS A MARKER OF DISEASE BURDEN, HEALTHCARE RESOURCE UTILISATION IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (BLOOD EOSINOPHIL COUNT AND COPD)

First published: 12/11/2013

Last updated: 01/04/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS4921

Study ID

28222

DARWIN EU® study

No

Study countries

Study description

The proposed study will use the United Kingdom's Optimum Patient Care Research Database (OPCRD) to explore the relationship between blood eosinophil count and future exacerbation risk in COPD. Additional analysis will also aim to validate blood eosinophil count as a reliable, stable and responsive measure to assess its utility as a marker of disease risk. Exploratory investigations will also seek to characterise features of COPD patients with eosinophilia in terms of their COPD stage, comorbid conditions and other clinical characteristics (respiratory symptoms, past history of exacerbations, risk factors).

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life












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Institution

Networks

Respiratory Effectiveness Group (REG)

-  Belgium
-  Denmark
-  France
-  Germany
-  Greece
-  Hungary
-  Italy
-  Netherlands
-  Spain
-  Sweden
-  United Kingdom

First published: 07/07/2021

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Network

ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Study timelines

Date when funding contract was signed

Planned: 01/11/2013

Actual: 08/11/2013

Study start date

Planned: 04/11/2013

Actual: 18/11/2013

Date of final study report

Planned: 30/04/2014

Actual: 30/07/2014

Sources of funding

- Other

More details on funding

Respiratory Effectiveness Group, Research in Real Life

Study protocol

[REG_COPD Eosinophil Study Protocol_8Nove_ADEPT APPROVED.pdf](#) (936.74 KB)

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:

Disease epidemiology

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To establish the relationship between blood eosinophil count and future COPD exacerbations.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

All patients with a physician diagnosis of COPD rather than a strict, spirometrically-defined COPD population.

Patients with following criteria were included:

- Have ≥ 1 recorded blood eosinophil count
 - ≥ 2 years of continuous medical records
 - o ≥ 1 baseline year immediately prior to the first recorded blood eosinophil count
 - o ≥ 1 outcome years immediately following the first recorded blood eosinophil count
 - Aged ≥ 40 years²
 - Have physician-diagnosed COPD i.e. Read coded diagnosis.
-

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

35000

Study design details

Outcomes

COPD exacerbations:1. Unscheduled hospital admission or A&E attendance for either COPD or lower respiratory events,2. An acute course of oral steroids prescribed with evidence of respiratory review, OR3. Antibiotics prescribed with evidence of respiratory review.

Data analysis plan

Phase 1: will assess whether a raised eosinophil count can predict future COPD exacerbations. The expected number of exacerbations will be modelled with a Poisson regression model. Significant predictors of raised eosinophil count will be included in the model, as well as other potential baseline confounders.Phase 2: will evaluate the presence and nature of change between successive blood eosinophil counts. A multinomial logistic regression will be used to compare the probability of decreasing/increasing the eosinophil count as function of therapy and exacerbationLogistic regression modeling will be used to evaluate the effect of different characteristics on probability of having a raised COPD eosinophil count.

Documents

Study publications

[Kerkhof, M., Sonnappa, S., Postma, D.S., Brusselle, G., Agusti, A., Anzueto, A...](#)

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), other

OPCRD

Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

Data sources (types), other

Prospective patient-based data collection, The Optimum Patient Care Research Database (OPCRD). OPCRD contains all records from primary care practices in the UK who subscribe to the Optimum Patient Care (OPC) respiratory review. The dataset consists of both routine primary care electronic patient records + patient-reported questionnaire data (for a subset of patients who completed disease-specific questionnaires as part of the review).

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