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

PURI
https://redirect.ema.europa.eu/resource/28222

EU PAS number
EUPAS4921

Study ID
28222

DARWIN EU® study
No

Study countries
United Kingdom

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 eosinophila in terms of their COPD stage, comorbid conditions and other clinical characteristics (respiratory symptoms, past history of exacerbations, risk factors).

Study status
Finalised

Research institution and networks

Institutions

Research in Real Life
First published: 01/02/2024
Last updated 01/02/2024
Institution

Networks

Respiratory Effectiveness Group (REG)
Belgium
Denmark
France
Germany
Greece
Hungary
Italy
Netherlands
Spain
Sweden
United Kingdom
First published: 07/07/2021
Last updated 04/06/2024
Network ENCePP partner

Contact details

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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 and secondary data collection

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 rasied eosinophil count can predict future COPD exacerbations. The expected number of exacerbations will be modelled with a Poisson regression model. Significant predictors of rasised 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

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