Investigating the possible role of BLood eosinophil counts in guiding ANti-inflammatory treatment of COPD exAcerbations (BLANCA)

First published: 20/12/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16875

Study ID

26154

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A matched historical database study among patients with COPD in the UK will be conducted. The index date is defined as the date of any exacerbation with a blood eosinophil count measurement available on the same day and with a one-year baseline and at least 6 weeks post index date. A dataset of unique patients from the Optimum Patient Care Research Database (OPCRD) will be used for analyses. Moreover, the Clinical Practice Research Datalink (CPRD) will be used to increase the number of available patients fitting the inclusion and exclusion criteria. The dataset from both the sources will be combined and duplicate records will be removed. A combined dataset of unique patients will be used for all the analyses. The study population will consist of patients with a COPD diagnostic Read code, with blood eosinophil counts recorded on an exacerbation date with no OCS and antibiotic use during the 2 weeks before the event and registered at general practices providing data to OPCRD (or CPRD) across the United Kingdom.

Study status

Finalised

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

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/12/2016

Actual: 09/12/2016

Study start date

Planned: 27/12/2016

Actual: 27/12/2016

Data analysis start date

Planned: 06/01/2017

Actual: 06/01/2017

Date of final study report
Planned: 15/05/2018

Actual: 24/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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

Medical procedure

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To study whether COPD patients with high blood eosinophil counts at the time of exacerbation prescribed oral corticosteroids with/without antibiotics experience decreased treatment failure as compared to those not prescribed oral corticosteroids.

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

Patients with a COPD diagnostic Read code, with blood eosinophil counts recorded on an exacerbation date with no OCS and antibiotic use during the 2 weeks before the event and registered at general practices providing data to OPCRD (or CPRD) across the United Kingdom.

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

2500

Study design details

Outcomes

The primary outcome is treatment failure (to be studied for 6 weeks outcome period), defined as additional prescription of antibiotic or oral corticosteroids course or respiratory-related accident and emergency (A&E) attendance or respiratory-related hospital attendance / admission. The secondary outcome is

healthcare resource utilisation in the outcome period of 6 weeks and additionally at a 1 year outcome period for both high blood eosinophil and non-high blood eosinophil patients treated with and without oral corticosteroids.

Data analysis plan

Exact matching for categorical variables and matching within a maximum calliper for continuous variables will be used to match patients using nearest neighbour variable mixed matching with a match maximum of 3:1 on the variables predictive of outcomes, without replacement. Multiple observations can exist for the same patient, but each observation will only be used once during the matching process.The odds of experiencing treatment failure as defined above in patients prescribed oral corticosteroids with/without antibiotics will be compared to those not prescribed oral corticosteroids. A conditional logistic regression analysis in the matched cohorts will be performed to study whether the association between therapy option and outcomes is modified by the blood eosinophil level, adjusted for variables causing residual confounding. In addition, conditional cox proportional hazard regression will be used to assess how therapy option is associated with time to hospital admission.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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

Unknown