Burden of disease in patients with COPD and high blood eosinophil counts (High eosinophils and COPD)

First published: 31/01/2017

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17544

EU PAS number

EUPAS17543

Study ID

17544

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Patients with COPD with high blood eosinophil counts (BEC) have an increased risk of exacerbations. This study aims to evaluate the role of high BEC measured during stable disease in the burden and costs of COPD in a broad real-life population of patients in the United Kingdom.An observational historical follow-up study will be performed using medical records data for patients (aged ≥40 years) with COPD, from the Optimum Patient Care Research Database (OPCRD) and the Clinical Practice Research Datalink (CPRD) The study has the following objectives:1.To study the association between high BEC at the time of stable COPD (i.e., no recent exacerbation and stable treatment during the study period) and the prospective exacerbation rate in different subgroups of patients with COPD defined by treatment regimen and smoking habits and to study whether this association is also found in patients with good adherence to ICS2. To study whether patients admitted to hospital for COPD exacerbation are more likely to be re-admitted if their pre-admission BEC is high3. A. To estimate mean all-cause and COPD-related health care resource use (HRU) and associated costs in 4 subgroups of patients who are at risk of exacerbations (i.e. a history of ≥2 exacerbations or ≥1 exacerbation leading to hospitalisation in the past 12 months) while receiving treatment with triple therapy, where the 4 subgroups are defined by the presence or absence of high BEC and current smoking habitsB. to compare HRU and costs with those for the total population of patients with COPD who have BECs available4.To study whether the presence of high BEC is associated with greater all-cause and COPD-related costs in the subsequent year and to study which other easily accessible characteristics drive future costs in patients with COPD.

Study status

Ongoing

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

Planned: 01/08/2016

Actual: 01/08/2016

Study start date
Planned: 15/09/2016

Actual: 17/11/2016

Data analysis start date
Planned: 03/10/2016

Actual: 31/01/2017

Date of interim report, if expected
Planned: 16/12/2016

Date of final study report
Planned: 17/04/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

161207_R03315_Non-intervention study protocol_Burden of eosinophilic COPD V3.1.pdf(1.17 MB)

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To study the role of high blood eosinophil counts in the burden and costs of COPD in a broad real-life population of patients in the UK

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

40000

Study design details

Outcomes

COPD exacerbation rate for objective 1, COPD-related short-term rehospitalisation for objective 2, COPD-related HRU and costs for objectives 3&4,

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Data analysis plan

Binomial regression will be performed to estimate the adjusted association between high BEC and COPD exacerbations for objective 1.Cox-regression will be performed to estimate the adjusted association between high BEC and rehospitalisation for objective 2.HRU and mean costs will be described for different subgroups of patients on triple therapy who are at risk of exacerbations for objective 3.A one- or two-step generalized linear model with

gamma distribution and log link will be used to perform regression analysis with total costs as the outcome variable for objective 4.

Data management

ENCePP Seal

Conflicts of interest of investigators

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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

No