Eosinophilic asthma phenotypes and associated clinical outcomes

First published: 24/09/2019

Last updated: 02/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS31500

Study ID

31501

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

We will conduct a historical database study to characterise risk in regard to eosinophilic and non-eosinophilic asthma phenotypes and associated characteristics.The study will include asthma patients, aged ≥13 years, who

had controller or reliever inhaler therapy prescribed in the most recent 12 months of electronic medical records (EMR) extracted from UK general practices delivering data to Optimum Patient Care Research Database (OPCRD) and Clinical Practice Research Datalink (CPRD). Patients need to have at least one blood eosinophil recorded after first asthma diagnosis.To better understand the heterogeneity of asthma two different strategies will be applied to identify phenotypes. Patients will be classified into different grades of likelihood of eosinophilic asthma based on blood eosinophil counts and clinical features. In addition, unsupervised cluster analyses will be performed to identify different phenotypes of asthma which will be compared with the predefined phenotypes.Demographics, diagnosed comorbidities, clinical characteristics, such as asthma severity and control and health care resource utilisation (HCRU) will be described and compared for different phenotypes (both predefined and identified clusters) over the last 12 months of EMR data.Among patients who had multiple blood eosinophil counts available, those with persistently high blood eosinophil counts will be compared with patients without or with intermittently high counts using a separate design. These groups will be characterized and compared in a baseline period and clinical outcomes & HCRU will be compared in a follow-up year, using the most recent eosinophil count as the index date.

Study status

Planned

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: 03/06/2019

Actual: 27/06/2019

Study start date
Planned: 15/10/2019

Data analysis start date
Planned: 01/11/2019

Date of interim report, if expected
Planned: 13/12/2019

Date of final study report
Planned: 01/04/2020

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

To describe and compare characteristics, such as asthma severity and control and health care resource utilisation (HCRU) of patients with predefined grades of likelihood of the eosinophilic asthma phenotype in a recent population of real-life patients with active asthma and to compare these phenotypes with phenotypes identified from unsupervised cluster analyses

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Age groups

Adolescents (12 to < 18 years)

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

400000

Study design details

Data analysis plan

Demographics, diagnosed comorbidities, clinical characteristics, such as asthma severity and control and HCRU of asthma patients will be described for the total population and for different phenotypes separately.Analyses will be repeated in the subpopulation of patients who were on the register of patients with active asthma that general practitioners maintain in the UK within the Quality and Outcomes Framework (QOF). Within this subpopulation characteristics will be also be compared between patients with and without severe asthma (as questionnaire data will be available for more detailed assessment of asthma control).K-means clustering will be used to identify clusters of eosinophilic phenotypes using all available characteristics.Patient groups distinguished based on the longitudinal pattern of eosinophil counts will be characterised and compared in a baseline period prior to the last eosinophil count and future clinical outcomes & HCRU will be compared in a follow-up year.

Documents

Study publications

Price DB, Rigazio A, Campbell JD, Bleecker ER, Corrigan CJ, Thomas M, Wenzel SE...

Kerkhof M, Tran TN, Soriano JB, Golam S, Gibson D, Hillyer EV, Price DB. Health...

Price DB, Bosnic-Anticevich S, Pavord ID, Roche N, Halpin DM, Bjermer L, Usmani...

Kerkhof M, Tran TN, van den Berge M, Brusselle GG, Gopalan G, Jones RC, Kocks J...

Price D, Wilson AM, Chisholm A, Rigazio A, Burden A, Thomas M, King C. Predicti...

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

No