Asthma and Type 2 Comorbidities - Real-life Characterisation of Patients with Active Asthma and Type 2 Asthma Comorbidities

First published: 09/08/2018

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25204

EU PAS number

EUPAS25203

Study ID

25204

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Asthma is a common long-term condition which is responsible for considerable morbidity, mortality and costs. There are several related conditions, involving type 2 inflammation which have been identified as affecting asthma outcomes. The nine T2 co-morbidities of interest are: eczema, allergic rhinitis, chronic rhinosinusitis, nasal polyps, urticaria, allergic conjunctivitis, food allergy, eosinophilic oesophagitis and anaphylaxis. Because of the common underlying disease process, it has been suggested that successful treatment of one might also improve related conditions.The frequency with which these conditions co-occur in patients with asthma has not yet been described, nor has the relationship between co-morbidity patterns with asthma severity and asthma-related resource utilisation.The aim of this study is to describe the frequency and interrelations of these conditions, and assess associations with asthma severity, asthma-related healthcare resource utilisation and costs, within a real-world asthma population.The prevalence of each co-morbidities pattern will be measured, and associations between co-morbidities described using likelihood ratios and principal component analysis. This will be used to select a subset of patterns, in which patient characteristics, asthma severity, healthcare resource utilisation and cost will be compared using multivariable regression models, in all patients and stratified by asthma severity, co-morbidity severity and activity, blood eosinophil count and age.

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

Actual: 01/02/2018

Study start date
Planned: 01/03/2018

Actual: 01/03/2018

Data analysis start date
Planned: 05/03/2018

Actual: 05/03/2018

Date of interim report, if expected
Planned: 29/06/2018

Actual: 22/06/2018

Date of final study report
Planned: 24/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Regeneron, Sanofi

Study protocol

180625_OPRI-1705_Study Protocol_Asthma T2 Comorbidities_V1.3.pdf(1.89 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 estimate the frequency of each combination of T2 co-morbidities in a real world active asthma population, and to select a limited set of common co-morbidity patterns for further investigation.To describe the overlap between these patterns and between individual co-morbidities within the patterns in terms of patient demography, and asthma severity, resource utilisation and costs.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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

Co-occurrence patterns of the co-morbidities will be visualised in frequency tables, and associations between co-morbidities measured using likelihood ratios. Associations of patterns with patient characteristics and health care resource utilisation and costs will be done using multivariable regression. Principal components analysis will be used to identify clustering of inter-related co-morbidities.

Data management

ENCePP Seal

Conflicts of interest of investigators

EUPAS25203-25207.pdf(17.74 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

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