The Impact of Exacerbation Burden on Lung Function Trajectory in a Broad Asthma Population and Severe Asthma Population (Exacerbation and lung function trajectory)

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Last updated: 02/07/2024

Study   Ongoing

Administrative details

EU PAS number

EUPAS31386

Study ID

32519

DARWIN EU® study

No

Study countries

☐ Bulgaria

☐ Canada

☐ Greece

- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

Severe asthma exacerbations may play a significant role in lung function decline through their potential contribution to airway remodelling through inducing spikes of pulmonary inflammation. This study aims to investigate if there is an association between exacerbation burden and lung function decline in a broad asthma patient population using longitudinal (minimum 5 years of follow-up), real-life data collected on a large scale. The value of this study is its focus on the key enduring evidence gaps in in the current literature - inpatient representativeness, follow-up time and analysis methodology that is not covered by available studies of exacerbation burden and lung function decline in asthma patients.Treatment targets that improve asthma control/reduce exacerbations would be of additional benefit if it can be demonstrated rigorously that this improvement is associated with better long-term lung function status, and therefore decreased risk of permanent airway obstruction and/or other asthma morbidities.

Study status

Ongoing

Research institutions and networks

Institutions

Optimum Patient Care (OPC)

☐ United Kingdom

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Institution   Not-for-profit

Networks

Respiratory Effectiveness Group (REG)

☐ Belgium

☐ Denmark

☐ France

☐ Germany

☐ Greece

☐ Hungary

☐ Italy

☐ Netherlands

☐ Spain

☐ Sweden

☐ United Kingdom

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Contact details

Study institution contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2018

Actual: 30/04/2018

Study start date

Planned: 31/08/2018

Actual: 15/10/2018

Data analysis start date

Planned: 01/07/2019

Actual: 31/07/2019

Date of final study report

Planned: 31/12/2019

Sources of funding

- Other

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPCG

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:

This study aims to investigate whether the burden of severe asthma exacerbations is associated with lung function decline in asthma patientsThe main objective of this study is to assess the role of exacerbation burden as a predictor of lung function declined in asthma patients with at least 5 years of lung function recording (follow-up) and 3 or more lung function readings (spirometry or PEF)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

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

100000

Study design details

Outcomes

Lung function decline measured by Forced expiratory value in 1 second (L) and/or Peak expiratory flow rate (L/minute).

Data analysis plan

The study will assess a historical cohort of patients diagnosed with asthma, who have 3 or more of either PEFR or FEV1 readings taken over a minimum of 5 years from their 18th birthday. The index date, i.e. the start of follow-up, will be the first date on which a lung function reading is recorded after age 18. Baseline is defined as the year prior to and including the index date.The association between exacerbation burden and lung function will be explored under a mixed-effects regression modelling approach. The variation in lung function trajectories between individual study subjects is accounted for by including a random intercept and slope of lung function over time at the patient level in the model. The relationship between exacerbation burden and the slopes of lung function is modelled by the interaction term of exacerbation burden and follow up time in years in the mixed effects model. Non-linear trajectories will be considered by the inclusion of time polynomials in the model

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

International Severe Asthma Registry

Data sources (types)

Disease registry

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