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

First published: 22/11/2019
Last updated: 02/07/2024





### Administrative details

EU PAS number	
EUPAS31386	
Study ID	
32519	
DARWIN EU® study	
No	
Study countries	
Bulgaria	
Canada	
Greece	

Ireland	
Italy	
Japan	
Corea, 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
First published: 01/02/2024
<b>Last updated:</b> 01/02/2024
Institution Not-for-profit

## **Networks**

Respiratory Effectiveness Group (REG)
Belgium
☐ Denmark
France
Germany
Greece
Hungary
Italy
☐ Netherlands
Spain
Sweden
United Kingdom
First published: 07/07/2021
<b>Last updated:</b> 04/06/2024



### 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:

#### 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

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### 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