# 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

Study | Ongoing

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/32519

**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 institution and networks

## Institutions

### Optimum Patient Care (OPC)
United Kingdom
**First published:** 01/02/2024
Last updated 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
Last updated
04/06/2024
Network
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:
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)

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**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).

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**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