

# Hidden Severe Asthma in Primary Care versus ISAR Cohort

**First published:** 11/03/2019

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS28611

### Study ID

33771

### DARWIN EU® study

No

### Study countries

☐ United Kingdom

### Study description

To identify, within asthma managed population, patients that have severe asthma but are “hidden” from specialist care using a large, real-life population-based cohort of patients in the UK. Then to compare the demographic and

clinical characteristics of the “hidden” patients with severe asthma identified in primary care to those managed in specialist care. Primary objectives: • To construct criteria for identifying severe asthma in primary-care EMR databases based on their treatment and measures of control. • To compare the characteristics of “hidden” patients with severe asthma in primary care to those managed in specialist care (ISAR). Secondary objectives: • To describe the demographic and clinical profile of patients with severe asthma managed exclusively in primary care and are hidden from specialist care. • To describe the demographic and clinical profile of patients treated at low dose ICS/LABA and experiencing exacerbations. These patients may be unrecognised as potentially severe asthma patients. • To create a criteria-template for identifying these patients with severe asthma in other countries

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## Study status

Finalised

## 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**

# 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

David Price [dprice@opri.sg](mailto:dprice@opri.sg)

**Study contact**

[dprice@opri.sg](mailto:dprice@opri.sg)

### Primary lead investigator

David Price

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 20/12/2018

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### **Study start date**

Actual: 01/02/2019

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### **Data analysis start date**

Planned: 01/03/2019

Actual: 01/03/2019

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### **Date of interim report, if expected**

Planned: 27/03/2019

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### **Date of final study report**

Planned: 02/09/2019

Actual: 20/02/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Astra Zeneca

# Study protocol

[Hidden Severe Asthma Protocol v0.5 060219.pdf](#) (360.57 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

**Main study objective:**

Primary:Construct criteria to identify severe asthma in primary care EMR databases based on their treatment and measures of control.Compare the characteristics of “hidden” patients with severe asthma in primary care to those managed in specialist care (ISAR).Secondary:To describe the hidden patients with severe asthmaTo create a template for identifying these patients in other countries

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

**Short description of the study population**

Patients with potentially severe asthma in a primary care setting in UK.

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**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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### **Special population of interest**

Other

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### **Special population of interest, other**

Asthma patients

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### **Estimated number of subjects**

200000

## Study design details

### **Outcomes**

Patients with severe asthma who are hidden from specialist care will be described according to their: Age, Sex, Smoking status, exacerbations, level of control, blood eosinophil count, adherence, prescribed medication and co-morbidities

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### **Data analysis plan**

Descriptive statistics on demographic and clinical characteristics will be provided for continuous and categorical variables. Summary statistics for continuous variables will be: Sample size (n) Percentage non missing Mean Variance/standard deviation Range (minimum-maximum) Median Inter-quartile range (25th and 75th percentile) Summary statistics for categorical variables will include: Sample size (n) Range (if applicable) Count and percentage by category (distribution) Characteristics of

patients with severe asthma in primary care and ISAR will be compared, group difference will be tested for statistical significance via Chi-square tests. Student t-test or one-way analysis of variance (ANOVA) will be applied to test for statistical significance for comparison of means. Statistical significance will be defined as  $p < 0.05$

## Documents

### Study results

[OPRI\\_1817\\_Hidden\\_Severe\\_Asthma\\_in\\_Primary\\_Care\\_vs\\_ISAR\\_final\\_report\\_V1.5.pdf](#)  
(1.03 MB)

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## 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)

Optimum Patient Care Research Database  
International Severe Asthma Registry

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No