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

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 20/08/2026

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

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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
Actual: 20/12/2018

Study start date
Actual: 01/02/2019

Data analysis start date
Planned: 01/03/2019

Actual: 01/03/2019

Date of interim report, if expected
Planned: 27/03/2019

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

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.

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)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

200.000

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-morbidites

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 missingMeanVariance/standard deviationRange (minimum-maximum)MedianInter-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)

Data management

Data sources

Data source(s)

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