ENLIGHTEN: Assessment of quality improvement in the International Severe Asthma Registry

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000510

EU PAS number

EUPAS1000000510

Study ID

1000000510

DARWIN EU® study

No

Study countries

☐ Argentina

- [ ] Belgium
- [ ] Brazil
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Estonia
- [ ] Greece
- [ ] India
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Singapore
- [ ] Spain
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study description

A prospective cohort study using data on eligible adults with severe asthma in ISAR (International Severe Asthma Registry). We will investigate how data quality and clinical practice in ISAR has changed over time using a combination

of joinpoint regression, interrupted time-series and time-to-event analyses.

Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 11/11/2023

Study start date

Planned: 01/02/2025

Data analysis start date

Planned: 01/02/2025

Date of interim report, if expected
Planned: 22/12/2025

Date of final study report
Planned: 15/12/2026

Sources of funding

- Other

More details on funding

Joint funding from AstraZeneca and Optimum Patient Care Global

Study protocol

ENLIGHTEN_Protocol_Final_25.02.05_clean.pdf(719.62 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:

Other

Study topic, other:

Investigation of data quality and clinical practice over time in patients with severe asthma

Study type:

Non-interventional study

Scope of the study:

Validation of study variables (exposure outcome covariate)

Data collection methods:

Primary data collection

Study design:

Prospective cohort study using the International Severe Asthma Registry (ISAR)

Main study objective:

To investigate data quality (completeness) and clinical practice (long-term oral corticosteroid use and severity of asthma when starting biologics) over time in the International Severe Asthma Registry

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

This study uses data on eligible patients with severe asthma contributing to the ISAR programme from those countries that have consented for their data to be used for research.

Age groups

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

People living with severe asthma

Estimated number of subjects

95568

Study design details

Setting

This is a prospective cohort study using the International Severe Asthma Registry, a global collaborative initiative to gather anonymous, longitudinal, real-life data for patients with severe asthma. ISAR provides a rich source of data for studies of symptoms, treatments and patient outcomes in people with asthma. A consistent goal of the ISAR is to improve data quality, which involves constant re-evaluation of existing data and how it might be enhanced.

Comparators

N/A

Outcomes

(1) Patients meeting 90% and 100% data quality standards

(2) Completeness of variables in ISAR

(3) Long-term oral corticosteroid use

(4) Biologic initiation

Data analysis plan

The analysis will use a combination of joinpoint regression (log-linear model and the weighted Bayesian Information Criterion (BIC) test with a parametric method), interrupted time-series approaches (creation of splines at fixed timepoints when changes are expected to occur) and time-to-event analyses (Kaplan-Meier and flexible parametric approaches) to evaluate differential time in discontinuing/reducing LTOCS by calendar year and asthma severity indicators and initiating biologics by calendar year.

Summary results

Findings from this study will be presented at the Respiratory Effectiveness Group (REG)
in March 2025. A report will be finalised by December 2025 and the work will be submitted to a peer-reviewed journal in December 2026.

Data management

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

Disease registry

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