Exploring different composite definitions of responders and non-responders to biologic treatment for severe asthma (FULL BEAM)

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Study Planned

Administrative details

EU PAS number

EUPAS104132

Study ID

104133

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Bulgaria
- [ ] Canada

- [ ] Colombia
- [ ] Denmark
- [ ] Greece
- [ ] India
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Poland
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study status

Planned

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

- [ ] United Kingdom

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Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | 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: 01/03/2022

Study start date
Planned: 02/05/2022

Date of interim report, if expected
Planned: 30/12/2022

Date of final study report
Planned: 30/04/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPRI Pte Ltd

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:

1)Define the study population To describe pre-biologic demographic, clinical and functional characteristics of patients initiating biologics, overall and by biologic class 2) Quantify levels of response and characterize patients by levels of response To operationally assess levels of response to biologics (from non-response to highest level of response) in individual domains

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Registry-based cohort study

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

4000

Study design details

Outcomes

Clinical remission and response to treatment. While clinical remission will be assessed in all patients irrespective of their status pre-biologic initiation, response can only be assessed in patients impaired when initiating the treatment. Impairment will be defined for each domain independently as: 1) exacerbations: ≥2 exacerbations in the year preceding biologic initiation, 2) long-term OCS use

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Data analysis plan

Objective 1 aims at describing the study population used in objectives 2 and 3. To this end, the pre-biologic asthma-related outcomes will first be described individually and in composite variables. For individual asthma-related outcomes, both continuous and categorical variables will be used. The distributions will be compared between initiated biologic class using t-tests, Kruskall Wallis tests, or Person’s Chi-squared tests as appropriate. The proportion of patients responding to biologics as defined in section 5 will be computed overall and by biologic classes, for each individual domain and

composite definition of response. Patient characteristics will be described by levels of response using means, standard deviations, medians and interquartile ranges for continuous variables and numbers and percentages for categorical variables.

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.

Composition of steering group and observers

ISAR FULL BEAM Steering Group & Observers.pdf(17.92 KB)

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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