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

PURI
https://redirect.ema.europa.eu/resource/104133

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 institution and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom
First published: 06/10/2015
Last updated
23/11/2016

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 b

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

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

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