Defining and Characterizing Responders to Biologic Treatment (BEAM)

First published: 26/11/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38288

Study ID

48128

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Germany

- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Democratic People's Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Singapore
- [ ] Spain
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study description

This is a registry cohort study in which we will operationally define responders to biologic treatment by clinical endpoints and describe their characteristics overall and per biologic class (anti-IgE and anti-IL5). Initially, response to a biologic therapy will be evaluated based on improvements of single domains including exacerbation rate, cumulative OCS dose, long-term OCS dose, asthma control and lung function from pre- to post-therapy. To avoid duplication of information, response will be examined for the first biologic only. The level of responsiveness will then be assessed based on the overlap of the following four domains: exacerbation rate, long-term OCS use, asthma control and lung function. Data will be sourced from the International Severe Asthma Registry (ISAR).

Study status

Finalised

Research institutions and networks

Institutions

Optimum Patient Care (OPC)

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Not-for-profit

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network | ENCePP partner

Contact details

Study institution contact

David Price dprice@opri.sg

Study contact

dprice@opri.sg

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2020

Actual: 01/03/2020

Study start date

Planned: 01/12/2015

Actual: 01/12/2015

Data analysis start date

Planned: 01/08/2020

Actual: 01/08/2020

Date of interim report, if expected

Planned: 01/11/2020

Actual: 01/11/2020

Date of final study report

Planned: 31/05/2022

Actual: 17/06/2022

Sources of funding

- Other

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

Study protocol

OPCG-2001_BEAM_Protocol_FINAL.pdf (1.09 MB)

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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To classify responders to biologic treatment by clinical and functional endpoints and describe their characteristics overall and per biologic drug class.

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 ≥18 years old who receive treatment according to GINA Step 5 or experience uncontrolled asthma at GINA Step 4 as per the definition of severe

asthma.
Patients who were included in the International Severe Asthma Registry (ISAR) after they had started biologic treatment will not be included in the study unless pre-treatment data is available.

Inclusion criteria:
- Patients 18 years or older, who are receiving treatment according to GINA (2018 Criteria) step 5 or are uncontrolled at step 4. Uncontrolled asthma is defined as having severe asthma symptoms or frequent exacerbations requiring systemic corticosteroids.
- Patients prescribed with anti-IL5/5R, anti-IgE or anti-IL4/IL13 during study period
- Available registry data prior to or on biologic therapy initiation date
- Available registry data from biologic initiation date until a follow-up visit that is closest to a 1-year period (min. 16 weeks) or until date of switching/stopping their first biologic
- Switched/stopped their first biologic before first follow-up visit or before 16 weeks (as nonresponse)

Exclusion criteria:
- Patients who received bronchial thermoplasty
- Patients who are <18 years old
- Patients with a follow-up visit less than 16 weeks after biologic initiation date (without switch/stop)

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

1609

Study design details

Outcomes

To operationally assess response to biologic therapy by clinical and functional endpoints including exacerbations, systemic corticosteroids, asthma control and lung function. To describe and compare baseline (pre-therapy) demographic, clinical and functional characteristics of response and non-response groups to overall biologic treatment and by biologic class.

Data analysis plan

We are assessing improvement from at/before biologic initiation to after biologic therapy across 4 main domains of clinical response: Lung function, exacerbation, Long-term OCS, Asthma Control. What classifies as an improvement for each domain has been classified in agreement with published literature (e.g. clinical trials data). Level of response is also ascertained via assessing the number of domains with a positive change that a patient had. Finally, a responder is identified if they show improvement in more than 50% of the clinical response domains from the total of domain they have non-missing

data for.

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.

Conflicts of interest of investigators

David Price_COI.pdf (50.59 KB)

Composition of steering group and observers

BEAM Steering Committee Members.pdf (37.69 KB)

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

Other

Data sources (types), other

Observational initiative with retrospective and prospective 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