Effectiveness across severe asthma biologic classes (Anti-IL-5 vs Anti IgE) in patients eligible for both (FIRE)

First published: 18/11/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38128

Study ID

45615

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia

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

Study description

This is a prospective cohort study in which we will use a propensity score weighting approach to examine the effectiveness of initiating Anti-IgE versus Anti-IL5 among patients who are eligible for both modalities. In Phase 1, the demographic and clinical characteristics among all participants who are eligible for both modalities will be studied. These include patients who have an elevated blood eosinophil count, total serum IgE level, 2 or more pre-therapy exacerbation and allergic mediated asthma. In Phase 2, the two study arms will be balanced using propensity score weighting. After this, using weighted longitudinal regression analysis, the two groups will be compared to describe the health outcomes between the groups. These include the rate of exacerbations, OCS use and healthcare resource utilization. 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

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Study contact

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Primary lead investigator

Price David

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2019

Actual: 15/03/2019

Study start date

Planned: 01/11/2019

Actual: 11/11/2019

Data analysis start date

Planned: 01/08/2020

Actual: 01/09/2020

Date of final study report

Planned: 31/12/2021

Actual: 19/01/2022

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

Study protocol

ISAR_OPCG1903_Effectiveness across Bx classes_Protocol 13 Aug 2020.pdf
(351.33 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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim is to describe the pattern of use and examine the impact on health outcomes of initiating biologic therapy in a real-world severe asthma population.

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

Severe asthma population in the International Severe Asthma Registry who are eligible for both anti-IL-5/5R and antiIgE, based on most frequent eligibility criteria (including those eligible and did not start biologic), at or before the date of initiating of the treatment, overall and per country.

Inclusion criteria:

1. 18 years or older
2. GINA (2018) Step 5 treatment
3. GINA (2018) Step 4 treatment and uncontrolled

Exclusion:

1. Patients who received bronchial thermoplasty

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

8395

Study design details

Outcomes

To describe and compare the demographic and clinical characteristics between the Anti-IgE and Anti-IL5 users, The two study arms will be balanced using propensity score weighting. Next, using weighted longitudinal regression analysis, the two groups will be compared to describe the health outcomes between the groups such as the rate of exacerbations, OCS use, healthcare resource utilization and lung function, if applicable.

Data analysis plan

The two groups will be identified based on those who initiated and maintained a biologic therapy (anti-IgE, anti-IL5/anti-IL5R, or anti-IL4R) for 6 months ("new biologic users"), and those who stayed on maintenance SCS therapy or used 4 or more courses of SCS bursts (10 mg/day) at the time and were also not on any biologic therapy ("high SCS users"). The two groups will then described and compared based on their demographic and clinical characteristics. Descriptive statistics will be provided for continuous and categorical variables. Summary statistics will be produced for variables measured on the interval or ratio scale, including sample size, mean and SD and categorical variables including range and the percentage by category. After propensity score matching, the two groups will be compared to describe outcomes via weighted longitudinal regression analyses such as negative binomial regression and generalized linear models depending on the outcome of interest.

Data management

ENCePP Seal

Conflicts of interest of investigators

200730_COI_David Price_V8.pdf(47.99 KB)

Composition of steering group and observers

Effectiveness Across Bx Classes_Steering Committee.pdf(11.46 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