Associations between biological and clinical response following treatment with anti-IL5/5R biologics (FLAME)

First published: 02/04/2025

Last updated: 15/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000531

Study ID

1000000531

DARWIN EU® study

No

Study countries

- Argentina
- Belgium
- Brazil
- Bulgaria

Canada
Colombia
Denmark
Estonia
France
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 registry-based historical cohort study of severe asthma patients who initiated anti-IL5/5R biologic treatments. Changes in clinical outcomes (lung function and exacerbations) and changes in a biomarker (blood eosinophil count) over time following initiation of the biologic will be related to each other and to baseline patient characteristics as well as to other prior and ongoing asthma treatments.

The main aim of the study is to identify patient characteristics associated with biological and/or clinical treatment failure at different times after initiation of anti-IL5/5R biologics and the extent to which these are linked or independent events.
This information will help clinicians in selecting the best treatment for patients and provide important evidence on the information that should be collected before and after biologic initiation.

Study status

Ongoing

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 17/11/2023

Actual: 17/11/2023

Study start date

Planned: 15/04/2025

Actual: 15/04/2025

Data analysis start date

Planned: 15/04/2025

Date of interim report, if expected

Planned: 22/12/2025

Date of final study report

Planned: 30/06/2026

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Joint funding from AstraZeneca and Optimum Patient Care Global for data collection. Funding from Optimum Patient Care Global for analysis of the data.

Study protocol

ISAR FLAME Protocol_Final Draft_24.09.02.pdf (558.6 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Historical cohort study using data from the International Severe Asthma Registry (ISAR)

Main study objective:

To identify and describe patient characteristics associated with biological and/or clinical treatment failure at different times after initiation of anti-IL5/5R biologics and the extent to which these are linked or independent events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

FASENRA

NUCALA

Medicinal product name, other

Anti-IL5/5R biologic treatments for asthma, Cinquair

Study drug International non-proprietary name (INN) or common name

BENRALIZUMAB

MEPOLIZUMAB

RESLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX10) benralizumab

benralizumab

(R03DX09) mepolizumab

mepolizumab

(R03DX08) reslizumab

reslizumab

Population studied

Short description of the study population

The study will use data from severe asthma patients enrolled in the International Severe Asthma Registry (ISAR) who initiated an anti-IL5/5R biologic treatment.

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

3000

Study design details

Setting

Adult patients enrolled in the ISAR who initiated treatment with an anti-IL5/5R biologic.

Comparators

N/A

Outcomes

Changes in blood eosinophil count (BEC) over time

Changes in lung function (forced expiratory volume (FEV1)) over time

Changes in exacerbation rate over time

Data analysis plan

Test for associations between changes in BEC and changes in FEV1 and exacerbations (compared to their baseline values) one year after biologic initiation, and identify factors that modify these associations or explain the

remaining variability.

Describe the different patterns of change over time in BEC, FEV1 and exacerbations following initiation of anti-IL5/5R treatments.

Test for associations between baseline patient characteristics and different patterns of change over time in BEC and/or FEV1 and exacerbations following initiation of anti-IL5/5R, taking into account the modifying factors identified in the first year (see (i) above).

Summary results

The study will reveal whether biological and/or clinical failure of anti-IL5/5R treatments in the short or long term can be predicted from patient characteristics known pre-biologic initiation, or whether subsequent failure can be predicted from early follow-up data.

This information will help clinicians in selecting the best treatment for patients and provide important evidence on the information that should be collected before and after biologic initiation.

Results will be published in international peer reviewed journals and at an international respiratory conference.

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.

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

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No