# Assessing the impact of earlier access to biologics on remission and natural course of asthma (GLEAM)

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## Administrative details

### **EU PAS number**

EUPAS100000530

### Study ID

100000530

#### **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

An examination of the association between the timing of biologic therapy initiation, disease progression, and remission probabilities in severe asthma.

### 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

Laboratory/Research/Testing facility

## Contact details

**ENCePP** partner

Study institution contact David Price dprice@opri.sg

Study contact

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Primary lead investigator David Price 0000-0002-9728-9992

Primary lead investigator

## **ORCID number:**

0000-0002-9728-9992

## Study timelines

## **Date when funding contract was signed** Planned: 17/11/2023 Actual: 17/11/2023

**Study start date** Planned: 01/03/2024 Actual: 01/08/2024

Data analysis start date Actual: 15/03/2025

Date of final study report Planned: 30/06/2025

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Pharmaceutical companies: AstraZeneca

Other: Optimum Patient Care Global

## Study protocol

GLEAM\_PROTOCOL\_Final\_25.03.15.pdf(622.3 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:** Observational study, historical cohort study

Main study objective:

Objective 1:

To describe the timing of biologic therapy initiation using various proxies of time to initiation

Objective 2:

To assess whether the timing of biologic therapy initiation is associated with the course of the disease in patients with severe asthma, including remission, biomarkers and individual clinical outcomes.

## Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

## Name of medicine DUPIXENT FASENRA NUCALA TEZSPIRE 210 MG - SOLUTION FOR INJECTION XOLAIR

## Name of medicine, other

Cinqair

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

DUPILUMAB MEPOLIZUMAB OMALIZUMAB RESLIZUMAB TEZEPELUMAB

### Anatomical Therapeutic Chemical (ATC) code

(R03DX05) omalizumab omalizumab (R03DX08) reslizumab reslizumab (R03DX09) mepolizumab mepolizumab (R03DX10) benralizumab benralizumab (R03DX11) tezepelumab tezepelumab (D11AH05) dupilumab

### Additional medical condition(s)

Severe asthma

## Population studied

#### Short description of the study population

Patients diagnosed with severe asthma from 27 countries.

### 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

Patients with severe asthma

### Estimated number of subjects

15000

## Study design details

### Setting

Data collected at a clinical setting from years 2017-2024

### Comparators

Early vs late biologic initiators

### Outcomes

Asthma clinical remission, exacerbation, Long-term OCS, asthma control, blood eosinophil count, Fractional exhaled nitric oxide

### Data analysis plan

Remission:

- Type: Yes / No, Univariable: Logistic regression

Clinical outcomes:

- Exacerbations, Type: count, Univariable: Negative binomial
- Total OCS, Type: Continuous, Univariable: Linear regression
- Asthma control, Type: Ordinal, Univariable: Ordinal logistic regression
- Lung function, Type: Continuous, Univariable: Linear regression

Biomarkers:

FeNO, Type: Continuous, Univariable: Median change from baseline to 3 months, 12 month, 2 yrs, 3 yrs (Linear or quantile regression)
BEC, Type: Continuous, Univariable: Median change from baseline to 3 months, 12 month, 2 yrs, 3 yrs (Linear or quantile regression)

## Summary results

Not yet completed.

## Data management

## Data sources

### Data source(s)

International Severe Asthma Registry Optimum Patient Care Research Database

## Data source(s), other CHRONICLE

Data sources (types)

Disease registry Electronic healthcare records (EHR)

## 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

Not applicable