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

First published: 28/03/2025

Last updated: 28/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000530

EU PAS number

EUPAS1000000530

Study ID

1000000530

DARWIN EU® study

No

Study countries

☐ Argentina

- [ ] Belgium
- [ ] Brazil
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Estonia
- [ ] 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

Institution **Educational Institution** **Laboratory/Research/Testing facility**

ENCePP partner

Contact details

Study institution contact

David Price

Study contact

dprice@opri.sg

Primary lead investigator

David Price

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: 30/05/2025

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

dupilumab

Additional medical condition(s)

Severe asthma

Population studied

Short description of the study population

Patients diagnosed with severe asthma from 26 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