Sustainability of response to biologics in severe asthma and predictors of late failure among patients in an international registry (SHINE)

First published: 23/10/2025

Last updated: 23/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000788

Study ID

1000000788

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Belgium
- [ ] Brazil

- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Estonia
- [ ] Greece
- [ ] 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

Study aims to characterise late failures—relapses occurring up to three years after remission is achieved at 12 months of biologic therapy.

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

Networks

International Severe Asthma Registry

Contact details

Study institution contact

David Price dprice@opri.sg

Study contact

dprice@opri.sg

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: 01/03/2023

Actual: 17/03/2023

Data analysis start date
Planned: 01/07/2025

Actual: 30/07/2025

Date of final study report
Planned: 15/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pharmaceutical companies: AstraZeneca

Other: Optimum Patient Care Global

Study protocol

ISAR SHINE_Protocol_25.09.18_clean.pdf (566.21 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

Herbal medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Observational longitudinal study

Main study objective:

• To describe the frequencies of late failure and the type and extent of domain failure attributed to remission failures

• To identify pre- and post-treatment characteristics associated with late failures

• To describe persistence of late failures and the potential role of switching biologic agent in regaining remission after late failure

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

CINQAERO

DUPIXENT

FASENRA

NUCALA

TEZSPIRE

XOLAIR

Medicinal product name, other

Cinqair

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

BENRALIZUMAB

DUPILUMAB

MEPOLIZUMAB

OMALIZUMAB

TEZEPELUMAB

Medical condition to be studied

Asthma

Additional medical condition(s)

Severe asthma

Population studied

Short description of the study population

Patients diagnosed with severe asthma from 25 countries

Age groups

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

Study design details

Setting

The study population will be extracted from the International Severe Asthma Registry database (data collected between 2017 and 2025). Eligibility criteria include having initiated biologic therapy, being adult at initiation, and having follow-up data for at least 2 years after initiation.

Comparators

Patient demographic and clinical characteristics measured pre-initiation of biologic treatment and after 12 months of follow-up.

Outcomes

The outcome of interest will be late failure, considered the first failure to meet three-domain remission definition (No exacerbations, no long-term oral corticosteroid use, partly or well-controlled asthma) recorded at a follow up occurring at least 24 months following biologic initiation.

Data analysis plan

Outcome details: Remission status

Type: Yes, No

Model: Logistic regression

Estimates: Odds ratios

Summary results

Not yet completed.

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

Yes

Data characterisation moment

after data extraction