Assessing the impact of remission at 12-months post-initiation of biologic therapy on long-term clinical outcomes of patients with severe asthma (SPOTLIGHT)

First published: 23/10/2025

Last updated: 23/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000789

Study ID

1000000789

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

Description of remission patterns and an assessment of the long-term impact of remission in patients with 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**

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network | **ENCePP partner**

International Severe Asthma Registry

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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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: 15/03/2024

Actual: 01/09/2024

Data analysis start date

Planned: 15/01/2025

Actual: 01/04/2025

Date of final study report

Planned: 01/11/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pharmaceutical companies: AstraZeneca

Other: Optimum Patient Care Global

Study protocol

SPOTLIGHT protocol_25.02.04_clean.pdf (518.25 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:

Objective 1: To describe the patterns of remission over time and the patient characteristics of various patterns of remission.
Objective 2: To investigate the effect of remission on long-term clinical outcomes of asthma between those that graduate to remission at 12-months post-initiation of biologic therapy compared to those that do not.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

CINQAERO

DUPIXENT

FASENRA

NUCALA

TEZSPIRE

XOLAIR

Name of medicine, other

Cinqair

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

BENRALIZUMAB

DUPILUMAB

MEPOLIZUMAB

OMALIZUMAB

RESLIZUMAB

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 26 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

Patients who met remission criteria in the first year of follow-up versus those who did not.

Outcomes

Asthma clinical remission, exacerbations, long-term OCS use, asthma symptom control, lung function.

Data analysis plan

Outcome details:

Remission status

- Type: Yes, No
- Model: Logistic regression
- Estimates: Odds ratios

Exacerbations

- Type: Count
- Model: Negative binomial
- Estimates: Rate ratios

Long-term OCS use
- Type: Yes, No
- Model: Logistic regression
- Estimates: Odds ratios

Asthma control
- Type: Uncontrolled: yes/no
- Model: Logistic regression
- Estimates: Odds ratios

Lung function
- Type: Continuous
- Model: Linear regression
- Estimates: Mean differences

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