

Impact of biologics on inhaled corticosteroids reduction (MOON LIGHT)

First published: 04/12/2025

Last updated: 25/06/2026

Study

Finalised

Administrative details

EU PAS number

EUPAS1000000855

Study ID

1000000855


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
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Study description

To evaluate the effect of biologic initiation on the level of inhaled corticosteroid, SABA, and triple therapy exposure among patients with severe asthma


Study status

Finalised

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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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: 01/06/2025

Actual: 02/06/2025

Data analysis start date

Planned: 01/07/2025

Actual: 15/07/2025

Date of final study report

Planned: 31/08/2026

Actual: 24/06/2026

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Pharmaceutical companies: AstraZeneca

Other: Optimum Patient Care Global

Study protocol

[ISAR MOON LIGHT_PROTOCOL_Final Draft_25.09.05_clean.pdf](#) (680.81 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:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Observational longitudinal study

Main study objective:

Objective 1: To calculate the extent of reduction in ICS, SABA, and triple therapy use after biologic initiation.

Objective 2: To identify potential predictors of successful down titration of ICS, SABA, and triple therapy use for those receiving biologic therapy.

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, Dupilumab, Mepolizumab, Omalizumab, Reslizumab, Tezepelumab

Population studied

Short description of the study population

Patients diagnosed with severe asthma from 26 countries enrolled in ISAR.

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). Patients meeting the following inclusion criteria will be included in this study

- Documented initiation of biologic therapy, AND

- Severe Asthma diagnosis (severe defined as ≥ 2 exacerbations and medium dose ICS/LABA OR high ICS/LABA)
- Age 18 years or older at the time of biologic initiation, AND
- Record of biologic initiation date, AND
- Pre-bx ICS dose data (before bx initiation date) and at least one follow-up visits with ICS dose data post-bx,
- Patient data / recorded assessment available in baseline

Patients with the following exclusion criteria will not be included in this study:

- Biologic received for other (non-asthma) conditions (e.g. Urticaria, atopic dermatitis, EGPA, CRSwNP without severe asthma)
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Comparators

reducers vs non-reducers of ICS dose

those that stepped down from triple therapy vs those that did not (patients on triple therapy in the baseline year).

reducers vs non-reducers of SABA (OPCRD only).

Outcomes

ICS reduction (mcg, continuous)

ICS reducer – baseline is higher than the final ICS dose at follow-up times (6 months, 1 year, 2 year)

ICS non-reducer – baseline is equal to or lower than the final ICS dose at follow-up times (6 months, 1 year, 2 year)

SABA prescriptions (count)

Triple therapy (binary [stepped down to dual – yes or no])

Data analysis plan

Logistic regression models will be used to test for associations between baseline characteristics (including year of biologic initiation) and the odds of being an ICS reducer vs non-reducer at 12 months and 24 months after biologic initiation.

Summary results

In this large, multinational real-world study of patients with severe asthma, initiation of biologic therapy was associated with gradual but durable reductions in inhaled corticosteroid dose, modest decreases in SABA use, and limited but measurable step-down from triple therapy over five years of follow-up. Although most patients remained on their baseline inhaled therapy intensity, a meaningful minority achieved clinically relevant and durable reductions, with strong year-on-year persistence once down-titration occurred. Marked variation between countries suggests that the extent of inhaled therapy reduction is influenced by local clinical practice and healthcare systems, and that greater de-escalation may be achievable in some settings. Predictors of reduction were few, indicating that opportunities for safe inhaled-therapy de-escalation extend across a broad patient population rather than being limited to specific phenotypes. These findings

provide robust global evidence (noting the observational nature of the data) that biologics can support inhaled therapy optimisation in routine clinical practice, reinforcing guideline recommendations to consider ICS tapering once asthma control is achieved.

Future work should focus on defining structured, evidence-informed pathways for step-down and evaluating clinical outcomes associated with inhaler de-escalation to further support personalised, corticosteroid-sparing care.

Documents

Study report

[ISAR MOON LIGHT_Study Report_26.06.17_Final.pdf](#) (3.67 MB)

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

Unknown

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes