Impact of biologics on inhaled corticosteroids reduction (MOON LIGHT)

First published: 04/12/2025

Last updated: 19/12/2025

Study Ongoing

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

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

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

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: 01/06/2025

Actual: 02/06/2025

Data analysis start date

Planned: 01/07/2025

Actual: 15/07/2025

Date of final study report

Planned: 28/02/2026

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:

Disease /health condition

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)

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

N/A

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