CLinical oUtcomes before and after biologic treatMent by bIologic class, by iNdividuAl biologic, and by subgroups of baseliNe characTeristics (LUMINANT)

First published: 12/11/2021

Last updated: 27/05/2026

Study Finalised

Administrative details

EU PAS number

EUPAS44027

Study ID

50332

DARWIN EU® study

No

Study countries

Argentina

Austria

Bulgaria

Canada
Colombia
Denmark
Greece
Ireland
Italy
Japan
Korea, Republic of
Kuwait
Mexico
Portugal
Saudi Arabia
Spain
Taiwan
United Arab Emirates
United Kingdom
United States

Study status

Finalised

Research institutions and networks

Institutions

Optimum Patient Care (OPC)

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Not-for-profit

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network | ENCePP partner

Respiratory Effectiveness Group (REG)

- Belgium
- Denmark
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Spain
- Sweden
- United Kingdom

First published: 07/07/2021

Last updated: 04/06/2024

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2021

Study start date

Planned: 01/04/2021

Data analysis start date

Planned: 01/11/2021

Date of final study report

Planned: 31/05/2023

Actual: 31/05/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

Study protocol

ISAR_LUMINANT_Protocol_Final_Clean_130921.pdf (758.74 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:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Registry-based longitudinal cohort study using a prospective international cohort

Main study objective:

To describe the ISAR cohort who initiate biologic treatment and examine clinical outcomes at 12 months by biologic class, and subgroups of patients, and compare these to those not initiated on biologic medications

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Registry-based longitudinal cohort study

Study drug and medical condition

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

OMALIZUMAB

MEPOLIZUMAB

RESLIZUMAB

BENRALIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX05) omalizumab

omalizumab

(R03DX09) mepolizumab

mepolizumab

(R03DX08) reslizumab

reslizumab

(R03DX10) benralizumab

benralizumab

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Eligible subjects are adults (≥18 years old) with severe asthma, defined as patients with uncontrolled asthma at GINA 2018 Step 4 or undergoing GINA 2018 Step 5 treatment at baseline, who have initiated a biologic after

enrolment in ISAR, with at least 2 visits recorded, including a visit pre or at biologic initiation and 1 follow up visit post biologic treatment initiation (visit ≥24 weeks and closest to 1 year to be selected) in addition to ISAR registry inclusion criteria (Table 1).

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

11.000

Study design details

Outcomes

Asthma exacerbations, asthma control, oral corticosteroid use and dose, healthcare utilisation, lung function, Inflammatory markers, asthma symptoms, lung function

Data analysis plan

Overall and by subset groups (type of biologics, individual biologics, and baseline characteristics), descriptive statistics for Section 5.1 Demographic Variables (Table 2) and Section 5.2 Clinical Variables (Table 3) will be provided for continuous and categorical variables accordingly: Descriptive statistics for the overall population and by subgroup of interest: •For variables measured on the interval or ratio scale, summary statistics produced will be: Sample size (n), Percentage nonmissing, Mean, Standard deviation, Range (minimum-

maximum), Median •Inter-quantile range (25th and 75th percentile) •For categorical variable the summary statistics will include: Sample size (n) •Range (if applicable) •Count and percentage by category (distribution) •Characteristics of study groups will be compared and tested for statistical significance via McNemar's tests for comparison of counts data, t-test, or one-way analysis of variance (ANOVA) for continuous variables.

Documents

Study report

LUMINANT Study Report v2_29.12.22_clean.pdf (1.47 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.

Composition of steering group and observers

Project Steering Committee Member_LUMINANT.pdf (39.01 KB)

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

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No