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: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS44027

Study ID

50332

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Bulgaria

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

Study status

Planned

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

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

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

Medical condition to be studied

Asthma

Population studied

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

11000

Study design details

Outcomes

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

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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.

Data management

ENCePP Seal

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