Biologic Usage Patterns, Clinical Outcomes and Healthcare Resource Utilization (CLEAR)

First published: 03/11/2022

Last updated: 02/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS49548

Study ID

49640

DARWIN EU® study

No

Study countries

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

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

Study status

Planned

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

Respiratory Effectiveness Group (REG)

☐ Belgium
☐ Denmark
☐ France
☐ Germany
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands

☐ Spain

☐ Sweden

☐ United Kingdom

First published: 07/07/2021

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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: 21/10/2020

Study start date

Planned: 01/02/2021

Data analysis start date
Planned: 24/09/2021

Date of final study report
Planned: 30/12/2022

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPRI

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:

Disease epidemiology

Main study objective:

The main objective is to describe the demographic and clinical characteristics (including biomarker characteristics), of five severe asthma patient groups based on patterns of biologic initiation (1. Initiated and switched, 2. Initiated and continued, 3. Initiated and stopped, 4. Not initiated but eligible for biologics, 5. Not initiated and not eligible for any biologics).

Study Design

Non-interventional study design

Cross-sectional

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

10000

Study design details

Outcomes

Demographic & clinical characteristics of 5 severe asthma patient groups will be described based on biologic initiation patterns initiation (1.initiated & switched, 2.initiated and continued, 3.initiated and stopped, 4.not initiated but eligible for biologics, 5.not initiated & not eligible for any biologics). The primary outcome for objective 2 is post-therapy or post-ISAR enrolment exacerbation. The secondary outcome variables are LTOCS dose, asthma control and healthcare resource utilization.

Data analysis plan

Descriptive statistics of the baseline (pre-therapy) Demographic & Clinical Variables for the five biologic utilization groups will be conducted for continuous & categorical variables accordingly. Continuous variables will be summarised using means, standard deviations, medians, ranges, and interquartile ranges. Categorical variables will be presented as counts and percentages. Standardized mean difference (SMD) will be used to quantify differences in both continuous and categorical variables between the biologic utilization groups at baseline. Once balance has been achieved across groups (initiators vs non-initiators, switchers, stoppers vs continuers), the following statistical model were applied to estimate parameters: Primary Outcome: exacerbation - a negative binomial regression (y=annual rate of exacerbation). Secondary

Outcomes: •Asthma control - multinomial logistic regression model (ordered) •LTOCS dose – Generalized linear model (GLM) with generalized estimation equation

Data management

ENCePP Seal

Composition of steering group and observers

ISAR CLEAR_Project Steering Committee Members.pdf(47.96 KB)

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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