Impact of Initiating Biologics In Patients on Long-Term OCS Or Frequent Rescue Steroids (GLITTER)

First published: 03/12/2020

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS33582

Study ID

40478

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Bulgaria
- [ ] Canada
- [ ] Colombia

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

Study description

Data will be sourced from the International Severe Asthma Registry (ISAR). Anonymized person-level data from 19 countries will be used for this analysis. ISAR has governance provided by the ISAR scientific steering committee, The Anonymous Data Ethics Protocols and Transparency (ADEPT) committee, an independent body of experts and regulators commissioned by the Respiratory Effectiveness Group (REG). This is a prospective cohort study in which we will use a propensity score weighting approach to examine the effectiveness of initiating biologic therapy versus continued usual care in severe asthma patients with high SCS use in the real-world settings. The study period is between 2017 and 2019. All study participants will have a history of high SCS use for at least 12 months before entrance into the study. High SCS use refers

either to maintenance SCS therapy for at least 1 year or using 4 or more courses of rescue SCS bursts (10 mg/day) for a 12-month period at study entry. We will then divide them into two groups: those who initiated and maintained a biologic therapy (anti-IgE, anti-IL5/anti-IL5R, or anti-IL4R) for ≥6 months (“new biologic users”), and those who stayed on maintenance SCS therapy or used 4 or more courses of SCS bursts (10 mg per day) at time and were also not on any biologic therapy(“high SCS users”). In Phase 1, the demographic and clinical characteristics between the two groups will be compared and studied. In Phase 2, the two study arms will be balanced using propensity score weighting. After which, using weighted longitudinal regression analysis, the two groups will be compared to describe the health outcomes between the groups. These include rate of exacerbations, SCS use, asthma control and incidence of comorbidity.

Study status

Ongoing

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: 15/01/2019

Actual: 15/01/2019

Study start date

Planned: 01/01/2018

Actual: 01/01/2018

Data analysis start date

Planned: 01/08/2020

Actual: 15/11/2020

Date of final study report

Planned: 01/07/2021

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:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The aim is to describe the pattern of use and examine the impact on health outcomes of initiating biologic therapy in a real-world severe asthma population.

Study Design

Non-interventional study design

Cohort

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

8395

Study design details

Outcomes

To describe the demographic, clinical features, medication uses and comorbidities of adult severe asthma population with high SCS use, comparing between those who initiated a biologic therapy and those that did not initiate biologic therapy. To examine the comparative effectiveness of initiating a biologic therapy in adult severe asthma population with high SCS, comparing to those who did not initiate biologic therapy. Outcomes include exacerbations, asthma control, reduction/discontinuation of SCS and SCS-related comorbidity incidence.

Data analysis plan

The clinical effectiveness of those that were exposed to high-dose systemic corticoSteroids (SCS) that initiated a biologic will be compared to those that remained on high-SCS. Primary outcome, exacerbation: As the dispersion of the data is expected to be high and as this outcome is conditional on the duration of follow-up, we plan to apply a negative binomial regression to estimate the reduced rate of exacerbation. Group comparisons will be made if interactions between groups is found. Secondary outcome, SCS dose: Generalized linear model (GLM) with generalized estimation equation (GEE) will be applied to estimate the reduced SCS dose across groups while accounting for intra-patient correlation. Secondary outcome, health resource utilization: The difference in the number of incident hospital or emergency room visits in the outcome period across groups will be examined similar to the primary outcome discussed above.

Data management

ENCePP Seal

Conflicts of interest of investigators

200730_COI_David Price.pdf(50.33 KB)

Composition of steering group and observers

GLITTER SC.pdf(70.65 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