Impact of biologic initiation on steroid burden and new-onset of potentially OCS-related outcomes in patients with severe asthma (SOLAR)

First published: 24/03/2023

Last updated: 02/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS104139

Study ID

104140

DARWIN EU® study

No

Study countries

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

- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Greece
- [ ] Hungary
- [ ] India
- [ ] 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

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Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | 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: 03/10/2022

Study start date
Planned: 02/01/2023

Date of interim report, if expected
Planned: 01/05/2023

Date of final study report
Planned: 31/03/2024

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPRI Pte Ltd

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:

1) To assess the change in OCS intake in the full follow-up period in biologic initiator patients and non-biologic patients. 2) To quantify the association between change in OCS intake and subsequent new onset of potentially OCS-related adverse outcomes all patients, AND/OR 3) To compare the risk of potentially OCS-related adverse outcomes between biologic and non-biologic patients.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Historic-cohort design

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

12814

Study design details

Outcomes

The total OCS dose at follow-up (which is the sum of long-term OCS dose and rescue steroid dose) will be measured. All three types of OCS dose will be categorized as: increased dose (<0% reduction), low dose reduction (0% to ≤50%), moderate dose reduction (>50% to ≤75%) and optimal dose reduction (>75% to ≤100%). It will also be determined if a patient reached ≤5mg total or long-term OCS dose. Occurrence of potential OCS related outcomes (Anxiety, Depression, Cerebrovascular accident, Osteoporosis and/or related fractures, Type II diabetes mellitus, progression of diabetes, Cataract/Glaucoma, Obesity (BMI≥30 kg/m3), Peptic Ulcer, Pneumonia, Obstructive Sleep Apnea, Renal Failure, Heart Failure, Myocardial Infarction, Thromboembolism, Pulmonary Embolism) will be determined.

Data analysis plan

Descriptive statistics of the baseline (pre-index date) demographic and clinical variables will be conducted and compared for each exposure groups (change in OCS or biologic vs non-biologic groups) as well as by data source (ISAR vs

OPCRD). Continuous variables will be summarised using means, standard deviations, medians, ranges and interquartile ranges. Categorical variables will be presented as counts and percentages. Logistic regression with IPTW-matching will be used to assess the likelihood of attaining low total OCS or LTOCS dose. Low OCS dose will be defined as ≤5mg of total OCS dose or LTOCS. Univariate and multivariable analyses will be performed for acute and chronic outcomes that are and are not recurrent. All analyses will be conducted with R version 4.1.0.

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

ISAR SOLAR Steering Group & Observers.pdf (29.32 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