Characteristics of type 2 asthma phenotypes and oral corticosteroid (OCS) use in the International Severe Asthma Registry (ISAR) (STAR)

First published: 05/10/2022

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS49201

Study ID

50241

DARWIN EU® study

No

Study countries

- ☐ Argentina
- ☐ Australia
- ☐ Bulgaria

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

Study status

Ongoing

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

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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: 11/02/2022

Actual: 11/02/2022

Study start date

Planned: 15/11/2022

Actual: 15/11/2022

Data analysis start date
Actual: 12/12/2022

Date of interim report, if expected
Planned: 09/01/2023

Date of final study report
Planned: 30/08/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Regeneron/Sanofi, Optimum Patient Care 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

Main study objective:

The main objective is to describe patients aged 18 years or older with GINA 4/5 asthma, enrolled in ISAR, by OCS use and biomarker distribution, Type 2 characteristics and individual biomarkers, prior to biologic initiation. An added objective is to describe those patients with low eosinophilic phenotypes and who have long-term OCS use prior to biologic initiation.

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

3404

Study design details

Outcomes

Demographic and clinical characteristics will be described for GINA Steps 4/5 patients with no, intermittent and long-term OCS use. The prevalence of type 2 characteristics, as defined by biomarkers or concomitant type 2 disease, will also be presented. Demographic and clinical characteristics will be described for GINA Steps 4/5 patients with low eosinophilic phenotypes (blood eosinophils <150 cells/microL) and long-term OCS use.

Data analysis plan

The final sample size will depend on the number of individuals with available data on biomarkers, OCS use and type 2 comorbidities. Analysis will be undertaken in STATA and R. As the study requires descriptive analyses, no inferential statistics will be performed. Continuous variables will be summarised using means, standard deviations, medians and interquartile ranges. Categorical variables will be shown as number and percentage.

Data management

ENCePP Seal

Composition of steering group and observers

ISAR STAR_Steering Group and Observers_ENCePP.pdf(17.94 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