Biologics in severe asthma: utilization patterns, causes for discontinuation and switches

First published: 03/01/2020

Last updated: 26/02/2024

Study Planned

Administrative details

EU PAS number

EUPAS32724

Study ID

32725

DARWIN EU® study

No

Study countries

Singapore

United Kingdom

Study description

To describe the use of biologics in patients with severe asthma, with respect to persistence and switch to another biologic, and how this relates to asthma outcomes.To describe the frequency, patterns, reasons and clinical outcomes for biologic treatment discontinuation and switching in a severe asthma cohort.To describe the demographical and clinical characteristics of severe asthma patients that discontinue or switch their biologic therapy, stratified by country.

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: 20/12/2018

Study start date
Planned: 31/10/2019

Data analysis start date
Planned: 01/06/2019

Date of final study report
Planned: 01/10/2019

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPCG

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

Drug utilisation

Main study objective:

To describe the use of biologics in patients with severe asthma, with respect to persistence and switch to another biologic, and how this relates to asthma outcomes

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

5.000

Study design details

Outcomes

To describe the frequency, patterns, reasons and clinical outcomes for biologic treatment discontinuation and switching in a severe asthma cohort. To describe the demographical and clinical characteristics of severe asthma patients that discontinue or switch their biologic therapy, stratified by country.

Data analysis plan

Stata version 14.2 SE and 15.1 MP/6 (College Station, TX, USA) will be used to conduct allstatistical analyses and data manipulations. All descriptive statistics will be done with datathat is not missing. For each variable with missing values, the percentage of missingness will be reported.

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.

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

Disease registry

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