

Descriptive Study of the Incidence of Malignancy in Patients with Severe Asthma Overall and Among Those Receiving Benralizumab and Other Therapies, a Post Authorization Safety Study

First published: 14/11/2018

Last updated: 27/06/2024

Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/50719>

EU PAS number

EUPAS26310

Study ID

50719

DARWIN EU® study

No

Study countries

Bulgaria

Denmark

Finland

Greece

Iceland

Ireland

Italy

Japan

Korea, Republic of

United States

Study description

This is a real-world, observational, prospective cohort study in patients with severe asthma recruited into the International Severe Asthma Registry (ISAR) and the US severe asthma registry (CHRONICLE) and followed-up for occurrence of new malignancies. The primary objective is to measure the incidence of malignancy in the overall severe asthma population as well as its relevant subgroups, including patients receiving benralizumab, patients receiving non-benralizumab biologics, and patients not receiving biologics. The secondary objective is to describe the clinical characteristics of new malignancy cases that develop in severe asthma patients and relevant subgroups.

Study status

Ongoing

Research institution and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated 01/02/2024

Institution

Optimum Patient Care (OPC)

United Kingdom

First published: 01/02/2024

Last updated 01/02/2024

Institution

Not-for-profit

Parexel International

Sweden

First published: 19/10/2010

Last updated 26/04/2024

Institution

Non-Pharmaceutical company

ENCePP partner

ISAR Registry: Optimum Patient Care Global Limited (OPC) UK

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated

08/08/2023

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

PAREXEL

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eileen Dareng

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:

21/03/2017

Actual:

21/03/2017

Study start date

Planned:

01/01/2018

Actual:

01/01/2018

Data analysis start date

Planned:

01/04/2021

Actual:

26/02/2021

Date of interim report, if expected

Planned:

31/12/2023

Actual:

29/11/2023

Date of final study report

Planned:

31/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

[D3250R00042-pass-csp-v4_Redacted.pdf\(391.09 KB\)](#)

[D3250R00042 - Protocol v.5_Redacted.pdf\(373.74 KB\)](#)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

D3250R00042

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

To measure the incidence of malignancy in the overall severe asthma population as well as its relevant subgroups, including patients receiving benralizumab, patients receiving non-benralizumab biologics, and patients not receiving biologics.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Real-world, observational, prospective cohort study in patients with severe asthma recruited into the International Severe Asthma Registry (ISAR) and the US severe asthma registry (CHRONICLE) and followed-up for occurrence of new malignancies

Study drug and medical condition

Name of medicine

Fasenra

Study drug International non-proprietary name (INN) or common name

BENRALIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX10) benralizumab

Medical condition to be studied

Neoplasm malignant

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

14000

Study design details

Outcomes

Incidence of malignancy, Describing malignancy cases that occurred

Data analysis plan

This is a descriptive study with primary objective to estimate the incidence rate for malignancies in 3 cohorts of the overall severe asthma population: patients receiving benralizumab, patients receiving non-benralizumab biologics, and patients not receiving

any biologics. Observed incidence rates will be presented together with nominal 95% exact confidence intervals (Clopper-Pearson). Difference in incidence rates between the cohorts will be presented with nominal 95% confidence intervals.

Documents

Study report

[D3250R00042 - Protocol v.2_Redacted.pdf](#)(629 KB)

[D3250R00042 - Protocol v.3_Redacted.pdf](#)(3.23 MB)

[D3250R00042 EUPAS26310-PASS-Interim study report_Redacted.pdf](#)(844.24 KB)

[D3250R00042- Second Interim Study Report_Redacted.pdf](#)(7.37 MB)

[D3250R00042-protocol-v1_Redacted.pdf](#)(527.12 KB)

[EUPAS26310_Malignancy PASS_ Third Interim Report_Redacted.pdf](#)(981.69 KB)

Study, other information

[D3250R00042 - Protocol v.2_Redacted.pdf](#)(629 KB)

[D3250R00042 - Protocol v.3_Redacted.pdf](#)(3.23 MB)

[D3250R00042 EUPAS26310-PASS-Interim study report_Redacted.pdf](#)(844.24 KB)

[D3250R00042-protocol-v1_Redacted.pdf](#)(527.12 KB)

Data management

Data sources

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