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: 07/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS26310

Study ID

50719

DARWIN EU® study

No

Study countries

- ☐ Argentina
- ☐ Bulgaria

- [ ] Canada
- [ ] Colombia
- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Greece
- [ ] Iceland
- [ ] India
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Saudi Arabia
- [ ] Singapore
- [ ] Spain
- [ ] Sweden
- [ ] Taiwan
- [ ] United Kingdom
- [ ] 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

Finalised

Research institutions 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

United States

First published: 19/10/2010

Last updated: 10/12/2024

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: 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

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

Actual: 28/11/2024

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 topic:

Disease /health condition

Human medicinal product

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

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

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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)

Malignancy PASS CSR Synopsis (EUPAS26310_NCT04991805).pdf(202.06 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

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 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