CROSSROADS-1: Treatment Outcomes among Tezspire Users: A Claims Data Study (20230159)

First published: 25/03/2024

Last updated: 09/12/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000062

Study ID

1000000062

DARWIN EU® study

No

Study countries

☐ United States

Study description

This will be a descriptive, retrospective cohort study conducted utilizing the IQVIA PharMetrics® Plus database to assess the reduction of asthma exacerbations and healthcare resource utilization among Tezspire users.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/06/2022

Actual: 08/06/2022

Study start date

Planned: 24/01/2024

Actual: 24/01/2024

Data analysis start date

Planned: 31/03/2025

Actual: 18/11/2024

Date of final study report

Planned: 01/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen 100%

Study protocol

Protocol-Published Amendment tezepelumab 20230159 1 .pdf(445.31 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

20230159

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Descriptive retrospective cohort study.

Main study objective:

Assess the reduction of asthma exacerbations resulting in hospitalizations, emergency visits, or outpatient visits and the reduction in exacerbation related health care resource use after initiation of Tezspire (post-index period) compared to the pre-index period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

TEZSPIRE 210 MG - SOLUTION FOR INJECTION

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

TEZEPELUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX11) tezepelumab

tezepelumab

Medical condition to be studied

Asthma

Additional medical condition(s)

Asthma

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

300

Study design details

Setting

The index date will be between December 2021 (Tezspire [tezepelumab-ekko] launch) and the latest data available at the time of study execution (January 2024). The pre-index period will be the 12-months preceding the index date. The post-index period will be the 12-months following Tezspire (tezepelumab-ekko) initiation.

Comparators

NA

Outcomes

Reduction of Annualized asthma exacerbation rate.

Data analysis plan

Categorical study variables will be reported as frequencies (counts and percentages). Continuous variables will be described by means, standard deviation (SD), median, and ranges. Asthma exacerbations will be reported as AAER (events per patient-year) assessed during the pre- and post-index, separately. One-sided paired t-tests will be used to test for differences in continuous outcomes observed between the pre- and post-index. McNemar-Bowker tests will be used to assess for pre-post differences in categorical variables.

Data management

Data sources

Data source(s), other

IQVIA Pharmetrics® Plus

Data sources (types)

Administrative healthcare records (e.g., claims)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes