CROSSROADS-2: Clinical Characteristics, Treatment Patterns, and Treatment Outcomes Among Users of Tezspire: An Electronic Medical Record (EMR) study (20220066)

First published: 22/03/2024

Last updated: 12/06/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000053

Study ID

1000000053

DARWIN EU® study

No

Study countries

☐ United States

Study description

Retrospective cohort study to describe the characteristics of patients treated with Tezspire (tezepelumab-ekko) in the real-world setting.
Additionally, this study will describe treatment patterns and asthma related clinical outcomes of patients initiating Tezspire.
Tezspire patients will be identified in the TriNetX Dataworks-USA network (a de-identified, longitudinal Electronic Medical Record (EMR)-derived dataset that includes outpatient and inpatient EMRs from 60 healthcare organizations (HCOs) across the US).

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.
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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: 07/11/2022

Actual: 07/11/2022

Study start date
Planned: 18/01/2024

Actual: 18/01/2024

Data analysis start date
Planned: 15/07/2025

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 Original tezepelumab 20220066 .pdf(478.3 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

20220066

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:

- Describe the clinical characteristics of new users of Tezspire.
- Describe the treatment patterns of new users of Tezspire at 6 and 12 months after treatment initiation (post-index period)
- Assess reduction of asthma exacerbations resulting in hospitalizations, emergency visits, or outpatient vis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

TEZSPIRE

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

TEZEPELUMAB

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients with severe asthma with asthma exacerbations in the baseline period.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 65 years)

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

583

Study design details

Setting

In the TriNetX Dataworks-USA database, patients who newly initiated Tezspire (tezepelumab-ekko) at the age of 12 or older in the United States will be identified. The first Tezspire (tezepelumab-ekko) initiation date for the patient will be defined as the index date for all objectives.

The index date will be between December 2021 (Tezspire [tezepelumab-ekko] launch) and the latest data available at the time of study execution (anticipated 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.

Outcomes

Outcomes for Primary Objective 1 will be baseline characteristics and include demographics, comorbidities, clinical asthma characteristics, and asthma-related medications, in the pre-index period.

Outcomes for Primary Objective 2 include measures of adherence, persistence, and discontinuation of Tezspire (tezepelumab-ekko) use in the follow-up period. Additionally, switches to other treatments will be captured in the follow-up period.

Outcomes for Primary Objective 3 include reduction of Annualized Asthma Exacerbation Rate (AAER).

Data analysis plan

For Objectives 1 and 2, all analyses will be descriptive, without hypothesis or statistical testing. Continuous measures will be reported as mean, SD (Standard Deviation), median, IQR (Interquartile Range) (Q1, Q3) and range (min, max); categorical measures will be reported as count and percent.

For Objective 3 and Exploratory Objectives, analyses will be descriptive.

Continuous measures will be reported as mean, SD (Standard Deviation), median, IQR (Interquartile Range) (Q1, Q3) and range (min, max); categorical measures will be reported as count and percent. Additionally, reduction in Annualized Asthma Exacerbation Rate (AAER) between pre- and post- Tezspire (tezepelumab-ekko) initiation time periods will be compared using Generalized estimating equations.

Data management

Data sources

Data source(s), other

TriNetX Dataworks-USA

Data sources (types)

Electronic healthcare records (EHR)

Non-interventional study

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