Incidence of Retinal Vasculitis With or Without Retinal Vascular Occlusion Among Eyes Treated With Approved Anti-Vascular Endothelial Growth Factor Agents in Neovascular Age-Related Macular Degeneration or Diabetic Macular Edema

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Last updated: 22/08/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS107730

Study ID

107731

DARWIN EU® study

No

Study countries

United States

Study description

This is a secondary data use, retrospective observational cohort study. The study will analyze anonymized electronic health record (EHR) data from private retina specialists in the United States to assess the incidence of retinal vasculitis (RV), RV with retinal vascular occlusion (RO), and intraocular inflammation (IOI) (including RV) with RO among eyes with neovascular age-related macular degeneration (nAMD) or diabetic macular edema (DME). Incidence will be assessed among eyes treated with intravitreal (IVT) anti-vascular endothelial growth factor (VEGF) agents. The EHR (Vestrum Health Database) records longitudinal information on patient diagnosis, treatments, and outcomes, which allows the assessment of incident adverse events (AEs) and the temporality of treatments relative to the AEs. The selected database also contains data on visual acuity (VA), which allows for the assessment of potential vision changes following the occurrence of an AE. Diagnosis of nAMD, DME, and AEs will be identified using International Classification of Diseases 9/10 Clinical Modification (ICD-9/10-CM) diagnosis codes. Although Vestrum Health data are available from 1 January 2014, the appropriate study period will be determined based on the amount of data accrued across all treatment agents of interest, taking into consideration any potential surveillance or reporting bias such as that due to increased awareness of these AEs following brolucizumab launch. Inclusion criteria: eyes diagnosed with nAMD or DME that received at least 1 anti-VEGF treatment during the study period following the date of the index diagnosis; patients who were 18 years or older at the index anti-VEGF treatment; eyes with at least one visit following the index anti-VEGF treatment. Exclusion criteria: eyes with an incident IOI, RV, or RO on or prior to the index anti-VEGF treatment date.

Study status

Ongoing

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

Contact details

Study institution contact

Trial Information Support Line TISL global-roche-genentech-trials@gene.com

Study contact

global-roche-genentech-trials@gene.com

Primary lead investigator

Gloria Chi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/10/2023

Study start date

Actual: 20/10/2023

Data analysis start date
Planned: 30/09/2026

Date of final study report
Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche, Ltd.

Study protocol

Prot CR45271 faricimab v2, Published Output-1_signed_20231206_Redacted.pdf (659.02 KB)

Prot CR45271 faricimab v3, Published Output-1_Redacted.pdf (706.13 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

CR45271

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Main study objective:

Assess and compare the incidence of RV, RV with RO, and IOI (including RV) with RO events across eyes treated with approved IVT anti-VEGF agents after diagnosis of nAMD or DME as recorded in the EHR database.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

AVASTIN

BEOVU

BYOOVIZ

EYLEA

LUCENTIS

VABYSMO

Medicinal product name, other

Cimerli

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

AFLIBERCEPT

BEVACIZUMAB

BROLUCIZUMAB

FARICIMAB

RANIBIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(S01LA04) ranibizumab

ranibizumab

(S01LA05) aflibercept

aflibercept

(S01LA06) brolucizumab

brolucizumab

(S01LA08) bevacizumab

bevacizumab

(S01LA09) faricimab

faricimab

Medical condition to be studied

Neovascular age-related macular degeneration

Diabetic retinopathy

Additional medical condition(s)

Diabetic macular edema

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

250.000

Study design details

Setting

The study will include patient eyes from the Vestrum Health database, which includes data from EHRs from private retina specialists in the United States. Diagnosis of nAMD, DME, and AEs will be identified using ICD-9/10-CM diagnosis codes. Eyes not coming from active practices in the Vestrum database will not be included. Although Vestrum Health data are available from 1 January 2014, the appropriate study period will be determined based on the amount of data accrued across all treatment agents of interest, taking into consideration any potential surveillance or reporting bias such as that due to increased awareness of these events following brolucizumab launch.

Outcomes

- Incidence of RV, RV with RO, and IOI (including RV) with RO events across eyes treated with approved IVT anti-VEGF agents after diagnosis of nAMD or DME;
- Summarize the demographic and clinical characteristics of study eyes;
- Among eyes with events, summarize the characteristics of anti-VEGF treatments received, including but not limited to the number of injections received, type of anti-VEGF agents received, time to event, and vision change and severe vision loss following the event

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Data analysis plan

The primary analyses involve identifying the occurrence of the following adverse events: RV, RV with RO, and IOI (including RV) with RO among eyes with nAMD or DME. Eyes with each retinal indication and event will be identified using ICD-9/10-CM codes. Among eyes with multiple indications, eyes will be assigned to the first retinal indication diagnosed. The incidence of RV, RV with RO, IOI (including RV) with RO may be summarized using n (%) patient eyes at risk with events, the number of events per 1,000 injections (or 10,000 injections, etc. as appropriate), or the incidence rate (number of events/eye-time). The relative risk of RV, RV with RO, and IOI (including RV) with RO events by different anti-VEGF agents compared to a reference agent will be calculated.

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), other

Vestrum Health United States

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Routine electronic health records from retina specialists

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