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A study investigating the effectiveness, safety and quality of life in participants with age related visual impairment (macular degeneration) who have switched to faricimab, under real world conditions in Germany

Submission date
06/09/2023

Recruitment status
No longer recruiting

Registration date
07/09/2023

Overall study status
Ongoing

Last Edited
17/07/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Neovascular age-related macular degeneration (nAMD) is a disease that causes damage to the light-sensitive layer at the back of the eye (retina) leading to loss of sharp fine detailed vision required for daily activities such as reading, driving, and recognizing faces. A group of medicines called anti-vascular endothelial growth factors (aVEGF) have been a great success in treating patients with nAMD. However, in the long term, real-world results seem to be declining and may vary. Faricimab is a drug for administration into the eye via a fine needle (intravitreal injection) treatment used in patients with nAMD. Faricimab is approved by the United States Food and Drug Administration and the European Commission for the treatment of nAMD. The main aim of this study is to gather knowledge by collecting long-term data on previously treated participants with nAMD and to better understand the effectiveness, safety, and influence on the quality of life of faricimab in previously treated patients with nAMD under real-world conditions.

Who can participate?
Patients aged at least 50 years old with nAMD

What does the study involve?
Participants will take part in this study for approximately 24 months. Participants treated with faricimab will be observed in this 24-month period and the corresponding long-term data will be collected.

Study doctors will collect information regarding the participants' age, gender, ethnicity, and relevant clinical parameters from interviews or medical examinations according to local practice. The details on faricimab therapy and reasons for changes, if applicable, will be recorded at each visit.

Additionally, the quality of life of the participants will also be assessed using a set of questionnaires called National Eye Institute Visual Function Questionnaire [NEI VFQ-25] and Short Form-36 Health Survey [SF-36] questionnaire. Participants are required to fill out these questionnaires at specified time points.

What are the possible benefits and risks of participating?
It is not intended that participants will receive any benefit from this study. The data collected might help in the better understanding of the limitations of the current therapies for nAMD, the reason for non-adherence, and the treatment patterns in a real-world setting.

There may be unknown or unforeseen risks, including privacy risks, associated with participating in this study.
Only the data available from routine clinical practice will be collected; thus, there could be some missing data.
The data to be captured for this study will be collected from the sites where diagnosis and treatment of disorders of the eye take place (ophthalmologic sites) and not from any other healthcare providers. Hence there may be an under-reporting of the data other than that related to eye and related disorders.

Where is the study run from?
Roche Pharma AG (Roche Germany)

When is the study starting and how long is it expected to run for?
November 2022 to June 2027

Who is funding the study?
Roche Pharma AG (Roche Germany)

Who is the main contact?
global.trial_information@roche.com

Contact information

Type(s)
Public

Contact name
Dr Clinical Trials

Contact details
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Grenzach-Wyhlen
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ML44059

Study information

Scientific Title
A non-interventional, multicenter study to investigate effectiveness, safety and quality of life in nAMD switch patients treated with faricimab under real world conditions in Germany

Acronym
PASSENGER

Study objectives
The aim of the study is to evaluate the effectiveness of intravitreal injection treatment of faricimab on maintaining vision in previously treated neovascular age related macular degeneration (nAMD) participants treated for the first time with faricimab under real-world conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/01/2023, Westphalia-Lippe Ethics Commission (Ethik-Kommission Westfalen-Lippe) (Gartenstr. 210–214, Munster, 48147, Germany; +49 (0)251 929 2460; ethik-kommission@aekwl.de), ref: 2022-847-f-S

Study design
Single-arm prospective multicenter non-interventional study

Primary study design
Observational

Study type(s)
Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Neovascular age related macular degeneration (nAMD)

Interventions
Participants will be observed for effectiveness, safety, and quality of life once every 4 weeks during the loading dose phase (if applicable) and thereafter according to routine clinical practice for treatment (approximately once every 8 weeks to once every 16 weeks) for 24 months. Participants will also be required to fill out certain questionnaires such as the National Eye Institute Visual Function Questionnaire [NEI VFQ-25] and Short Form-36 Health Survey [SF-36] during the study. Optical coherence tomography (OCT) images of the participants that are

collected within the scope of routine clinical practice during this study, will be additionally analysed by imaging experts in three different reading centers.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Faricimab

Primary outcome(s)
Mean change from baseline in visual acuity measured per local practice at Week 52

Key secondary outcome(s))
1. Percentage of participants with an extended treatment interval without losing >4 letters in best-corrected visual acuity (BCVA) compared to baseline measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 and Week 104
2. Percentage of participants with an extended treatment interval compared to baseline measured by ETDRS Letter Score at Week 52 and Week 104
3. Percentage of participants in different treatment intervals compared to baseline measured using data collected on the electronic case report form (eCRF) after 52 Weeks
4. Percentage of participants in different treatment intervals compared to baseline measured using data collected on the eCRF after 104 Weeks
5. Mean change from baseline in visual acuity assessed using ETDRS Letter Score at Week 104
6. Mean change from baseline in central subfield thickness (CST) measured by the reading center using OCT from baseline up to Week 104
7. Mean change from baseline in central point thickness (CPT), measured by the investigator using OCT from baseline up to Week 104
8. Percentage of participants with the absence of intraretinal fluid (IRF) within the ETDRS Grid measured by the investigator using OCT from baseline up to Week 104
9. Percentage of participants with the absence of subretinal fluid (SRF) within the ETDRS Grid measured by the investigator using OCT from baseline up to Week 104
10. Percentage of participants with absence of sub-retinal pigment epithelium fluid (Sub-RPE fluid) within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104
11. Percentage of participants with absence of IRF and SRF within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104
12. Percentage of participants with absence of IRF, SRF and Sub-RPE fluid within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104
13. Percentage of participants with pigment epithelial detachment (PED) within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104
14. Percentage of participants with no or with clinically insignificant fluid within the ETDRS grid measured using OCT from baseline up to Week 104
15. Regime of switch of therapy measured using data collected on the eCRFs from baseline up to Week 104
16. Number of injections after treatment initiation with faricimab measured using data collected on the eCRF from baseline up to Week 104
17. Number of faricimab injections measured using data collected on the eCRF at Weeks 52 and 104

18. Number of reasons for therapy switch to faricimab given by the participants measured using data collected on the eCRF from baseline up to Week 104
19. Percentage of participants with treatment adherence and non-adherence measured using data collected on the eCRF up to Week 52
20. Percentage of participants with treatment adherence and non-adherence measured using data collected on the eCRF up to Week 104
21. Number of reasons for treatment non-adherence given by participants measured using data collected on the eCRF up to Week 104
22. Number of reasons for therapy switch from faricimab measured using data collected on the eCRF from baseline up to Week 104
23. Number of reasons for discontinuation of faricimab measured using data collected on the eCRF from baseline up to Week 104
24. Mean change from baseline in NEI VFQ-25 measured using NEI VFQ-25 Questionnaire at Weeks 52 and 104
25. Mean change from baseline in SF-36 score measured using SF-36 Questionnaire at Weeks 52 and 104
26. Mean score of NEI VFQ-25 measured using NEI VFQ-25 Questionnaire at baseline, Weeks 52 and 104
27. Mean score of SF-36 measured using SF-36 Questionnaire at baseline, Weeks 52 and 104
28. Percentage of participants with serious adverse events (SAEs), non-serious AEs and AEs of special interest (AESIs) up to approximately 48 months

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/07/2024:

1. Signed informed consent
2. Diagnosis of nAMD
3. Is at least 50 years old
4. Previously treated with an (anti) vascular endothelial growth factor (aVEGF)-drug (at least 3 doses) but no longer than 36 months since the first aVEGF injection (study eye) with clinical features of diabetic retinopathy (e.g.: microaneuryms, hemorrhages, etc.)
5. The last injection of the previous aVEGF has to be longer than 4 weeks before the first faricimab injection
6. Active nAMD, defined as persistent IRF and/or SRF on OCT despite treatment with aVEGF therapy or participants who could benefit from treatment intervals beyond their current standard treatment
7. BCVA in the study eye between 30 and 80 letters of ETDRS at first faricimab treatment

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Previous inclusion criteria:

1. Signed informed consent
2. Diagnosis of nAMD
3. Is at least 50 years old
4. Previously treated with an (anti) vascular endothelial growth factor (aVEGF)-drug (at least 3

doses) but no longer than 24 months since the first aVEGF injection (study eye)
5. The last injection of the previous aVEGF has to be longer than 4 weeks before the first faricimab injection
6. Active nAMD, defined as persistent IRF and/or SRF on OCT despite treatment with aVEGF therapy or participants who could benefit from treatment intervals beyond their current standard treatment
7. BCVA in the study eye between 30 and 80 letters of ETDRS at first faricimab treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Sex
All

Key exclusion criteria
1. Off-label use of faricimab
2. Previously treated with photodynamic therapy and retinal laser therapy (study eye)
3. Other retinal disease/intraocular condition (e.g., diabetic retinopathy, diabetic macular oedema, myopia >-6 diopter, angioid streaks, vision-reducing cataract) that, in the opinion of the investigator, could have an influence on the visual acuity (study eye)
4. Medical history of diabetes type 1 or 2
5. Participation in any other ophthalmological interventional and/or non-interventional study
6. Previously treated with faricimab (study eye); however, the first faricimab treatment may have occurred up to 12 weeks prior to enrollment
7. Pregnant and/or breastfeeding

Date of first enrolment
28/06/2023

Date of final enrolment
27/06/2025

Locations

Countries of recruitment
Germany

Study participating centre
Augenabteilung am St. Franziskus-Hospital
Munster

Germany
48145

Study participating centre
Augenarztpraxis Dr.Mihaescu & Kollegen
Würzburg
Germany
97080

Study participating centre
MVZ Augenzentrum am Berliner Ring
Würzburg
Germany
97080

Study participating centre
Augentagesklinik am Spreebogen Berlin
Berlin
Germany
10559

Study participating centre
AUGENZENTRUM auf der Insel,
Pfaffenhofen an der Ilm
Germany
85276

Study participating centre
Südblick GmbH - Augenzentrum Prinz 25; Makula & Drye Eye Center
Augsburg
Germany
86150

Study participating centre
Augenärzte Hamburg Dr. Kaupke MVZ GmbH
Hamburg
Germany
22587

Study participating centre
Augenheilkunde Oberricklingen Hannover
Germany
30459

Study participating centre
St. Elisabeth Krankenhaus Köln Hohenlind Köln
Germany
50935

Study participating centre
Dietrich-Bonnhöffer-Klinikum Neubrandenburg
Germany
17036

Study participating centre
Augenzentrum Frankfurt Prof. Koch und Dr. Deuchler
Germany
60549

Study participating centre
Institut für Augenheilkunde Halle Halle
Germany
06114

Study participating centre
Praxis Dr. Roxana Fulga Köln
Germany
50968

Study participating centre
Augenklinik Petrisberg Trier
Germany
54296

Study participating centre
Chiemsee Augen Tagesklinik Prien
Germany
83209

Study participating centre
Augenzentrum Schildergasse Köln
Germany
50667

Study participating centre
Augenklinik Stralsund Stralsund
Germany
18435

Study participating centre
Augenklinik Dardenne Bonn
Germany
66113

Study participating centre
Asklepios HH-Nord/Heidberg Hamburg
Germany
22417

Study participating centre
Sankt Gertrauden-Krankenhaus Berlin
Germany
10713

Sponsor information

Organisation
Roche Pharma (Roche Germany)

Funder(s)

Funder type
Industry

Funder Name
Roche Pharma AG (Roche Germany)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes