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A study to assess the safety, biological activity, tolerability and processing by the body of RO7200394 in participants with macular edema secondary to central retinal vein occlusion

Submission date 25/04/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/04/2023	**Overall study status** Completed	
Last Edited 24/07/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
The retina is a light-sensitive layer at the back of the eye. It receives a blood supply that provides oxygen and nutrients through the central retinal blood vessel (artery). Blood drains from the retina and leaves the eye through the central retinal vein. Blockage of the central retinal vein (CRVO) leads to fluid accumulating in the central part of the retina at the back of the eye called the macula (macular edema). This reduces the eye's ability to distinguish the details and shapes of objects (visual acuity).
The study drug RO7200394 is being developed to treat macular edema secondary to CRVO. RO7200394 is an experimental drug. Health Authorities have not yet approved RO7200394 for the treatment of CRVO, or any other disease. Lucentis® and Ozurdex® are each approved separately but treatment with both drugs at the same time is not approved.

The purpose of this study is to test RO7200394 and to study the effects of the drug on the body (pharmacodynamics) in participants with CRVO relative to Lucentis® alone or Lucentis® combined with Ozurdex®. For this purpose, fluid within the eye (aqueous humor) and images of the back of the eye will be analysed.

Who can participate?
Participants with macular edema secondary to CRVO aged ≥40 years old

What does the study involve?
Participants will need to be a part of this study for about 32 weeks (including the screening period). All participants need to attend monthly study visits for the entire study duration (28 weeks). The study will have three parts:

1. Screening Period: Potential participants will be screened to check if they are eligible to participate in the study. Screening visits will take place up to 28 days before the study starts.

2. Treatment Period: During this period participants will be randomly assigned to one of the three groups: Arms A, B or C in a 3:3:2 ratio to receive RO7200394, Lucentis® or Ozurdex® along with Lucentis® for up to Week 24. Participants will have a total of 7 clinic visits i.e., Weeks 1, 4, 8, 12, 16, 20 and 24.

- Arm A: Participants will receive RO7200394, as an injection into the eye (intravitreal injection [IVT]) on Day 1, Week 4 and Week 8 followed by Lucentis® IVT injection at Weeks 12, 16, 20 and 24.

- Arm B: Participants will receive Lucentis® as an IVT injection on Day 1, Week 4 and Week 8 followed by RO7200394, IVT injection at Weeks 12, 16 and 20. At Week 24 participants will receive Lucentis® as an IVT injection.

- Arm C: Participants will receive Ozurdex® which is an IVT device placed once in the eye containing the drug dexamethasone on Day 1 along with Lucentis® as an IVT injection from Day 1 to Week 24.

Safety follow-up visit/period: Participants must return to the clinic 4 weeks after treatment is complete for a final visit at week 28.

What are the possible benefits and risks of participating?
During a part of the trial, the participants will receive approved drugs like Lucentis® and Ozurdex® which can help treat CRVO. The participants will not receive any additional benefit from participating in this study, but the information that is learned may help people with macular edema with CRVO in the future. Participants may have side effects from the drug or procedures used in this study, and they can be mild to severe, and they can vary from person to person.

Risks associated with RO7200394:
RO7200394 has had limited testing in humans and all the side effects are not known at this time. Potential side effects may include swelling (inflammation) in the eye, bleeding at the front of the eye (conjunctival hemorrhage), eye pain, spots in the vision (vitreous floaters), and increased pressure within the eye (intraocular pressure).

Risks Associated with Lucentis®:
Lucentis may cause inflammation of the eye, bleeding in the back of the eye, visual disturbances, eye pain, small particles, or spots in the vision (floaters), bloodshot eye, eye irritation, abnormal sensation or a feeling of having something in the eye, increased tear production, inflammation or infection of the eyelid margins, dry eye, redness or itching of the eye and increased eye pressure and also may cause sore throat, nasal congestion, runny nose, headache and joint pain.

There may be a decreased sharpness of vision, swelling of a section of the eye (uvea, cornea), inflammation of the front part of the eye (cornea), small marks on the surface of the eye, blurred vision, temporary loss of vision, pain, irritation or bleeding at the site of injection, bleeding in the eye, discharge from the eye with itching, redness and swelling (conjunctivitis), light sensitivity, eye discomfort, eyelid pain and irritation, urinary tract infection, low red blood cells count (with symptoms such as tiredness, breathlessness, dizziness, pale skin), anxiety, cough, nausea, allergic reactions like rash, hives, itching and skin reddening. In some rare cases, it may cause inflammation and bleeding in the front part of the eye, a sac of pus on the eye, and changes in the central part of the eye surface.

Risks Associated with Ozurdex®:
Ozurdex may cause elevated pressure within the eye, which may be associated with optic nerve damage, visual sensitivity (acuity) and field defects, a small, opaque area that usually forms near the back of the lens (posterior subcapsular cataract formation), secondary eye infection from germs including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Risks Associated with IVT injection:
IVT injection may cause increased eye pressure, severe inflammation or infections inside and/or outside the eye (known as endophthalmitis and/or periocular infections), separation of the retina from the underlying tissue (retinal detachment or retinal tears), bleedings into the eye bulb, or cataracts (cloudiness of the eye's lens). One may experience temporary visual disturbances after the injection into the eye and after the associated eye examinations.

Participants may experience itching, numbness, blurred vision, or discomfort from the numbing drop (anesthetic) that will be given before the IVT injection.

Risks Associated with eye tests:
Fluorescein Angiography a test that requires an injection of a dye into a vein in the arm may cause some discomfort at the needle site, and the injection of the dye could irritate the vein or cause redness, swelling or redness at the injection site. The dye may cause nausea and vomiting, allergic reactions, feeling faint, breathing difficulties or shock.

As a part of Ophthalmoscopy Exam drops are used to make the black part of the eyes larger (dilate the pupils) which may cause ocular stinging, blurred/glared vision and/or sensitivity to light. Other uncommon effects of the drops may include dizziness, increased sweating, increased blood pressure, abnormal heart rhythm, slow heart rate, and/or increased eye pressure that could cause eye damage.

A pre-intraocular injection procedure which involves administering an antiseptic called povidone iodine which may cause a burning sensation or irritation in the eye because of the antiseptic use.

Aqueous Humor sampling
This procedure involves a very fine needle that is inserted into the front of the eye which may cause infection, inflammation, bleeding, pain, and reduction of the pressure inside the eye or damage to structures inside the eye, including the lens.

There may be a risk in exposing an unborn child to the study treatment and not all potential consequences are known at this time. Women must take precautions to avoid exposing an unborn child, or during breastfeeding a baby, to the study treatment. Participants who are pregnant, or are currently breastfeeding, cannot take part in this study.

Where is the study run from?
F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?
December 2022 to January 2025

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
global-roche-genentech-trials@gene.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Clinical Trials

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BP44241

Study information

Scientific Title
A phase Ib, multicenter, randomized, double masked, active comparator-controlled study to investigate the biological activity, safety, tolerability, pharmacokinetics and pharmacodynamics of RO7200394 in participants with macular edema secondary to central retinal vein occlusion

Study objectives
The main purpose of the study is to assess pharmacodynamic (PD) effects of RO7200394 and Lucentis® on aqueous humor (AH) molecular biomarkers in participants with macular edema secondary to central retinal vein occlusion (CRVO).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2023, Advarra IRB (6100 Merriweather Dr., Suite 600, Columbia, MD 21044, USA; +1-410-884-2900; rebecca.forney@advarra.com), ref: none provided

Study design
Phase Ib multicenter randomized double-blind interventional active comparator-controlled cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Macular edema secondary to central retinal vein occlusion

Interventions
Participants will be randomized to Arms A, B and C in a 3:3:2 ratio through the interactive voice and web response system (IxRS).

Arm A: Participants will receive RO7200394, 4 milligrams (mg), intravitreal (IVT) injection on Day 1 and every 4 weeks (Q4W), (a total of 3 injections) up to Week 8. At Week 12, the treatment will then be switched to Lucentis®, 0.5 mg, IVT injection, every 4 weeks (total of 4 injections) until Week 24.

Arm B: Participants will receive Lucentis®, 0.5 mg, IVT injection, on Day 1 and Q4W, (a total of 3 injections), up to Week 8. At Week 12, the treatment will then be switched to RO7200394, 4 mg, IVT injection (total of 3 injections), Q4W until Week 20, followed by one final IVT injection of Lucentis® at Week 24.

Arm C: Participants will receive Ozurdex® an intravitreal implant containing dexamethasone, 0.7 mg along with Lucentis®, 0.5 mg, IVT injection on Day 1. Participants will continue receiving Lucentis®, 0.5 mg, IVT, Q4W up to Week 24.

Intervention Type
Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
RO7200394, ranibizumab (Lucentis®), dexamethasone (Ozurdex®)

Primary outcome(s)
1. Arms A and B: Change in aqueous humor (AH) molecular biomarkers measured using multiplex immunoassay technology from Baseline to Week 12
2. Arms A and B: Change in AH molecular biomarkers within the Arm measured using multiplex immunoassay technology from Week 12 to Week 24

Key secondary outcome(s))
1. Number of participants with ocular adverse events (AE) as assessed by data collected in an electronic case report form (eCRF) from initiation of the study up to Week 28
2. Number of participants with systemic AEs as assessed by data collected in an electronic case report form (eCRF) from initiation of the study up to Week 28

Completion date
15/01/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/12/2023:
1. Aged ≥40 years at the time of signing the informed consent form (ICF)
2. Body mass index (BMI) of ≤40 kg/m2 at screening
3. Consent to AH collection
4. Ability to comply with the study protocol

Ocular inclusion criteria for study eye:
1. Treatment-naïve macular edema due to CRVO prior to Day 1 and confirmed by the Central Reading Center (CRC)
2. Decreased best corrected visual activity (BCVA) primarily due to CRVO
3. Macular thickening secondary to retinal vein occlusion (RVO) with central subfield thickness (CST) ≥300 µm at screening
4. Adequately clear ocular media and adequate pupillary dilation to allow the acquisition of good-quality retinal images

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Previous inclusion criteria as of 25/09/2023:
1. Aged ≥40 years at the time of signing the informed consent form (ICF)
2. Body mass index (BMI) of ≤40 kilograms per metre square (kg/m^2) at screening
3. Consent to AH collection
4. Ability to comply with the study protocol

Ocular Inclusion Criteria for Study Eye:
1. Treatment-naïve macular edema due to CRVO with initial symptoms and diagnosis ≤ 45 days prior to Day 1 and confirmed by the Central Reading Center (CRC).
2. Decreased best corrected visual activity (BCVA) primarily due to CRVO with early treatment diabetic retinopathy study (ETDRS) score of 80 to 20 letters (both inclusive) at screening.
3. Macular thickening secondary to retinal vein occlusion (RVO) with central subfield thickness (CST) ≥ 325 micrometer (µm), as measured on Spectralis spectral domain optical coherence tomography (SD-OCT), or ≥ 315 µm, as measured on Cirrus SD-OCT or Topcon SD-OCT, at screening.
4. Adequately clear ocular media and adequate pupillary dilation to allow the acquisition of good quality retinal images.

Previous inclusion criteria:
1. Aged ≥40 years at the time of signing the informed consent form (ICF)
2. Body mass index (BMI) of ≤40 kilograms per metre square (kg/m^2) at screening
3. Consent to AH collection
4. Ability to comply with the study protocol

Ocular Inclusion Criteria for Study Eye:
1. Treatment-naïve macular edema due to CRVO diagnosed ≤ 45 days prior to Day 1 and confirmed by the Central Reading Center (CRC).
2. Decreased best corrected visual activity (BCVA) primarily due to CRVO with early treatment diabetic retinopathy study (ETDRS) score of 80 to 20 letters (both inclusive) at screening.
3. Macular thickening secondary to retinal vein occlusion (RVO) with central subfield thickness (CST) ≥ 325 micrometer (µm), as measured on Spectralis spectral domain optical coherence tomography (SD-OCT), or ≥ 315 µm, as measured on Cirrus SD-OCT or Topcon SD-OCT, at screening.
4. Adequately clear ocular media and adequate pupillary dilation to allow the acquisition of good quality retinal images.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Sex
All

Total final enrolment
50

Key exclusion criteria
Current exclusion criteria as of 21/12/2023:
1. Any known hypersensitivity to fluorescein, any of the excipients of the drug(s) used, dilating eye drops, or any anesthetics and antimicrobial drops
2. Previous clinically significant adverse reactions to intraocular biologics (e.g., thromboembolic events, intraocular inflammation)
3. Use of any systemic (e.g., oral/intravenous/intraarticular) corticosteroids and/or chronic use of inhaled or topical steroids ≤ 4 weeks prior to Day 1, or any such treatment planned for the duration of the study
4. History of idiopathic or autoimmune-associated uveitis in either eye
5. Active periocular, ocular, or intraocular inflammation or infection (including suspected) in either eye on Day 1
6. Any of the following infectious diseases: Positive test for human immunodeficiency virus (HIV), history of active hepatitis B and C, active syphilis, active tuberculosis, symptomatic herpes zoster ≤12 weeks prior to screening
7. Participation in a clinical study for a non-ocular disease ≤60 days prior to Day 1, or ≤5 half-lives between the last exposure to study treatment in the previous study and Day 1 for the present study (whichever period is longer)

8. Use of prior systemic anti-vascular endothelial growth factor (VEGF) treatment ≤24 weeks prior to Day 1, or any such treatment planned for the duration of the study
9. Prior use of anti-tumor necrosis factor drugs

Ocular exclusion criteria for study eye:
1. Increase of ≥15 letters in BCVA ETDRS score between screening and Day 1
2. Any current or history of ocular condition which, in the opinion of the Investigator, is currently causing or may contribute to irreversible vision loss due to a cause other than macular edema due to CRVO in the study eye
3. History of retinal detachment or macular hole (Stage 3 or 4)
4. Advanced or uncontrolled glaucoma or intraocular pressure [IOP] >25 mmHg despite treatment
5. Tractional retinal detachment, vitreomacular traction, full thickness macular hole or epiretinal membrane involving the fovea or disrupting the macular architecture in the study eye, as evaluated by the Investigator, and described in the CRC manual
6. Diagnosis of diabetic retinopathy (DR), DME, nAMD, geographic atrophy, and myopic choroidal neovascularization as assessed by the investigator
7. Active rubeosis, angle neovascularization, neovascular glaucoma, or neovascularization of the disc (NVD), or neovascularization elsewhere (NVE)
8. Any other intraocular surgery (e.g., pars plana vitrectomy, scleral buckle, glaucoma surgery, corneal transplant, or radiotherapy)
9. Any prior or current treatment for macular edema due to CRVO e.g., laser or pharmacological
10. Panretinal photocoagulation in the study eye at any time prior to Day 1 or anticipated ≤2 weeks of study start on Day 1
11. Any prior or current treatment with e.g., tissue plasminogen activator, ocriplasmin, C3F8, air or periocular injection
12. Any prior intervention with verteporfin photodynamic therapy, diode laser, transpupillary thermotherapy, or vitreo-retinal surgery including sheathotomy
13. Any prior steroid implant use including dexamethasone intravitreal implant (Ozurdex®) and fluocinolone acetonide intravitreal implant (Iluvien)
14. Prior periocular pharmacological or IVT treatment for other retinal diseases
15. Any active intra- or periocular infection on Day 1
16. Active intraocular inflammation (i.e., Standardization of Uveitis Nomenclature [SUN] criteria >0 or NEI vitreous haze grading >0) on Day 1

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Previous exclusion criteria as of 25/09/2023:
1. Any known hypersensitivity to fluorescein, any of the excipients of the drug(s) used, dilating eye drops, or any anesthetics and antimicrobial drops
2. Previous clinically significant adverse reactions to intraocular biologics (e.g., thromboembolic events, intraocular inflammation)
3. Use of any systemic (e.g., oral/intravenous/intraarticular) corticosteroids and/or chronic use of inhaled or topical steroids ≤ 4 weeks prior to Day 1, or any such treatment planned for the duration of the study
4. History of idiopathic or autoimmune-associated uveitis in either eye
5. Active periocular, ocular, or intraocular inflammation or infection (including suspected) in either eye on Day 1
6. Any of the following infectious diseases: Positive test for human immunodeficiency virus (HIV), history of active hepatitis B and C, active syphilis, active tuberculosis, symptomatic herpes zoster ≤ 12 weeks prior to screening
7. Participation in a clinical study for a non-ocular disease ≤ 60 days prior to Day 1, or ≤ 5 half-lives between the last exposure to study treatment in the previous study and Day 1 for the

present study (whichever period is longer).
8. Use of prior systemic anti-vascular endothelial growth factor (VEGF) treatment ≤ 24 weeks prior to Day 1, or any such treatment planned for the duration of the study.
9. Prior use of anti-tumor necrosis factor drugs.

Ocular Exclusion Criteria For Study Eye:
1. Symptoms, or diagnosis, or history of CRVO > 45 days before Day 1
2. Increase of ≥ 15 letters in BCVA ETDRS score between screening and Day 1
3. Any current or history of ocular condition which, in the opinion of the Investigator, is currently causing or may contribute to irreversible vision loss due to a cause other than macular edema due to CRVO in the study eye
4. History of retinal detachment or macular hole (Stage 3 or 4)
5. Advanced or uncontrolled glaucoma
6. Tractional retinal detachment, vitreomacular traction, full thickness macular hole or epiretinal membrane involving the fovea or disrupting the macular architecture in the study eye, as evaluated by the Investigator, and described in the CRC manual
7. Diagnosis of diabetic retinopathy (DR), DME, nAMD, geographic atrophy, and myopic choroidal neovascularization as assessed by the investigator
8. Active rubeosis, angle neovascularization, neovascular glaucoma, or neovascularization of the disc (NVD), aphakia or pseudophakia
9. Any other intraocular surgery (e.g., pars plana vitrectomy, scleral buckle, glaucoma surgery, corneal transplant, or radiotherapy)
10. Any prior or current treatment for macular edema due to CRVO e.g., laser or pharmacological
11. Panretinal photocoagulation in the study eye at any time prior to Day 1 or anticipated ≤ 2 weeks of study start on Day 1
12. Any prior or current treatment with e.g., tissue plasminogen activator, ocriplasmin, C3F8, air or periocular injection
13. Any prior intervention with verteporfin photodynamic therapy, diode laser, transpupillary thermotherapy, or vitreo-retinal surgery including sheathotomy
14. Any prior steroid implant use including dexamethasone intravitreal implant (Ozurdex®) and fluocinolone acetonide intravitreal implant (Iluvien)
15. Prior periocular pharmacological or IVT treatment for other retinal diseases
16. Any active intra- or periocular infection on Day 1
17. Active intraocular inflammation (i.e., Standardization of Uveitis Nomenclature [SUN] criteria > 0 or NEI vitreous haze grading > 0) on Day 1

Ocular Exclusion Criteria For Non-study Eye
1. Non-functioning non-study eye

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Previous exclusion criteria:
1. Any known hypersensitivity to fluorescein, any of the excipients of the drug(s) used, dilating eye drops, or any anesthetics and antimicrobial drops
2. Previous clinically significant adverse reactions to intraocular biologics (e.g., thromboembolic events, intraocular inflammation)
3. Use of any systemic (e.g., oral/intravenous/intraarticular) corticosteroids and/or chronic use of inhaled or topical steroids ≤ 4 weeks prior to Day 1, or any such treatment planned for the duration of the study
4. History of idiopathic or autoimmune-associated uveitis in either eye
5. Active periocular, ocular, or intraocular inflammation or infection (including suspected) in either eye on Day 1

6. Any of the following infectious diseases: Positive test for human immunodeficiency virus (HIV), history of active hepatitis B and C, active syphilis, active tuberculosis, symptomatic herpes zoster ≤ 12 weeks prior to screening
7. Participation in a clinical study for a non-ocular disease ≤ 60 days prior to Day 1, or ≤ 5 half-lives between the last exposure to study treatment in the previous study and Day 1 for the present study (whichever period is longer).
8. Use of prior systemic anti-vascular endothelial growth factor (VEGF) treatment ≤ 24 weeks prior to Day 1, or any such treatment planned for the duration of the study.
9. Prior use of anti-tumor necrosis factor drugs.

Ocular Exclusion Criteria For Study Eye:
1. Diagnosis or history of CRVO > 45 days before Day 1
2. Increase of ≥ 15 letters in BCVA ETDRS score between screening and Day 1
3. Any current or history of ocular condition which, in the opinion of the Investigator, is currently causing or may contribute to irreversible vision loss due to a cause other than macular edema due to RVO in the study eye
4. History of retinal detachment or macular hole (Stage 3 or 4)
5. Advanced or uncontrolled glaucoma
6. Tractional retinal detachment, vitreomacular traction, full thickness macular hole or epiretinal membrane involving the fovea or disrupting the macular architecture in the study eye, as evaluated by the Investigator, and described in the CRC manual
7. Diagnosis of diabetic retinopathy (DR), DME, nAMD, geographic atrophy, and myopic choroidal neovascularization as assessed by the investigator
8. Active rubeosis, angle neovascularization, neovascular glaucoma, aphakia or pseudophakia
9. Any other intraocular surgery (e.g., pars plana vitrectomy, scleral buckle, glaucoma surgery, corneal transplant, or radiotherapy)
10. Any prior or current treatment for macular edema due to CRVO e.g., laser or pharmacological
11. Panretinal photocoagulation in the study eye at any time prior to Day 1 or anticipated ≤ 2 weeks of study start on Day 1
12. Any prior or current treatment with e.g., tissue plasminogen activator, ocriplasmin, C3F8, air or periocular injection
13. Any prior intervention with verteporfin photodynamic therapy, diode laser, transpupillary thermotherapy, or vitreo-retinal surgery including sheathotomy
14. Any prior steroid implant use including dexamethasone intravitreal implant (Ozurdex®) and fluocinolone acetonide intravitreal implant (Iluvien)
15. Prior periocular pharmacological or IVT treatment for other retinal diseases
16. Any active intra- or periocular infection on Day 1
17. Active intraocular inflammation (i.e., Standardization of Uveitis Nomenclature [SUN] criteria > 0 or NEI vitreous haze grading > 0) on Day 1

Ocular Exclusion Criteria For Non-study Eye
1. Non-functioning non-study eye

Date of first enrolment
16/06/2023

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
United States of America

Study participating centre
Erie Retinal Surgery Inc
300 State St., Suite 201
Erie
United States of America
PA 16507

Study participating centre
Austin Clinical Research
9707 Anderson Mill Road, Suite 100
Austin
United States of America
TX 78750

Study participating centre
Retina Consultants of Texas (Bellaire)
4460 Bissonnet St. Suite 200
Bellaire
United States of America
TX 77401

Study participating centre
Cumberland Valley Retina Consultants
1150 Opal Ct
Hagerstown
United States of America
MD 21740

Study participating centre
Sierra Eye Associates
950 Ryland Street
Reno
United States of America
NV 89502

Study participating centre

Wagner Macula & Retina Center
6160 Kempsville Circle, Suite 120B
Norfolk
United States of America
VA 23502

Study participating centre
Retina Consultants of Texas
17350 Saint Luke's Way, #120
The Woodlands
United States of America
TX 77384

Study participating centre
Retinal Consultants of AZ (Retina Research Institute, LLC)
15401 N. 29th Ave
Phoenix
United States of America
AZ 85053

Study participating centre
Texas Retina Associates
801 W. Randol Mill Road, Suite #101
Arlington
United States of America
TX 76012

Study participating centre
Florida Retina Institute
8786 Perimeter Park Boulevard
Jacksonville
United States of America
FL 32216

Study participating centre
Bay Area Retina Associates
365 Lennon Lane, Suite 250
Walnut Creek
United States of America
CA 94598

Study participating centre
Emanuelli Research and Development Center, LLC
452 Ave. Rivera Aulet
Arecibo
United States of America
PR 00612

Study participating centre
California Eye Specialists Medical Group Inc.
2619 E Colorado Blvd. #150
Pasadena
United States of America
CA 91107

Study participating centre
Retina and Vitreous of Texas
2727 Gramercy, Suite 200
Houston
United States of America
TX 77025

Study participating centre
Retinal Consultants Medical Group, Inc.
5775 Greenback Lane
Sacramento
United States of America
CA 95841

Study participating centre
Charleston Neuroscience Institute - [Retina Consultants of (Charleston)]
9565 Hwy 78 Building 300
Ladson
United States of America
SC 29456

Study participating centre
Piedmont Eye Center
116 Nationwide Drive
Lynchburg

United States of America
VA 24502

Study participating centre
Specialty Retina Center
6280 W. Sample Road, Suite 202
Coral Springs
United States of America
FL 33326

Study participating centre
Barnet Dulaney Perkins Eye Center
4800 N 22nd St
Phoenix
United States of America
AZ 85016

Study participating centre
The Retina Institute
2201 S. Brentwood Blvd
Brentwood
St Louis
United States of America
63144

Study participating centre
Mississippi Retina Associates
1200 North State Street
Jackson
United States of America
39202

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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