ForPatients
by Roche

Age-Related Macular DegenerationNeovascular Age-related Macular Degeneration

A Clinical Trial to Test an Ocular Implant that Releases Ranibizumab Compared with Eye Injections of Ranibizumab in Patients with Wet Age-Related Macular Degeneration (Archway)

A Phase III Study to Evaluate the Port Delivery System Implant With Ranibizumab Compared With Monthly Ranibizumab Injections in Participants With Wet Age-Related Macular Degeneration (Archway)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03677934 GR40548

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Phase III, Multicenter, Randomized, Visual Assessor-Masked, Active-Comparator Study of the Efficacy, Safety, and Pharmacokinetics of the Port Delivery System With Ranibizumab in Patients With Neovascular Age-Related Macular Degeneration

Trial Summary:

Study GR40548 is a Phase III, randomized, multicenter, open-label (visual assessor [VA]-masked), active-comparator study designed to assess the efficacy, safety, and pharmacokinetics (PK) of 100mg/ml delivered via the Port Delivery System with ranibizumab (PDS) compared with ranibizumab intravitreal injections at 0.5 mg (10 mg/mL) in participants with neovascular age-related macular degeneration (nAMD).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03677934 GR40548
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 50 Years	No

How does the Archway clinical trial work?

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This is a US-only clinical trial recruiting people aged 50 years or older who have a type of eye disease called ‘neovascular age-related macular degeneration’, also known as wet AMD. This trial is testing an ocular implant (a small device inserted into your eye through the sclera, the white part of your eye) intended to release a drug called ranibizumab over a prolonged period of time, compared with the currently approved ranibizumab treatment injections.

How do I take part in this clinical trial? If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor.

If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests and procedures may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial and what other treatments are available so that you may decide if you still want to take part. If you are female, and are not currently pregnant but can become pregnant, you will need to take contraceptive medication while you are taking part in the clinical trial for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin). You will have about a 2 in 3 chance of receiving the ocular implant and about a 1 in 3 chance of receiving ranibizumab injections. Neither you nor your clinical trial doctor may choose the group you will join.

- Either you will be given an implant, which contains ranibizumab, in your eye on Day 1 of the clinical trial. This implant releases ranibizumab into your eye over time. Once the implant is in place, it will be refilled with ranibizumab every 6 months for about 2 years (this is 3 total refills in 2 years, after the first implant filled with ranibizumab is placed in the eye). The ocular implant is an experimental device, which means that the FDA has not approved it. The implant is slightly bigger than a grain of rice.
- Or you will be given injections of ranibizumab directly into your eye every 4 weeks for about 2 years (this is 24 injections in total over 2 years). The ranibizumab dose used for injections directly into your eye is approved by the FDA.

How often will I be seen in follow-up appointments, and for how long? If you take part in this clinical trial, whichever treatment you are given, you will need to go to the clinic every month for about 2 years to have your vision checked, eye exams, eye imaging tests, health assessments and blood tests to look at how your body is responding to the

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ranibizumab treatment (and, if you are a woman who can become pregnant, you will have a pregnancy test at specified visits). At the clinic, you will also be asked to complete a survey about your eyesight. Patients who have been given an eye implant as part of this clinical trial need to go to the clinic for two extra visits on Day 2 and Day 7 after the surgery.

What happens if I'm unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for you or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03677934

Inclusion Criteria:

- Age #50 years, at time of signing Informed Consent Form
- Initial diagnosis of exudative neovascular age-related macular degeneration (nAMD) within 9 months prior to the screening visit
- Previous treatment with at least three anti-vascular endothelial growth factor (anti-VEGF) intravitreal injections for nAMD per standard of care within 6 months prior to the screening visit
- Demonstrated response to prior anti-VEGF intravitreal treatment since diagnosis
- Best-corrected visual acuity (BCVA) of 34 letters or better

Exclusion Criteria:

- Subfoveal fibrosis or subfoveal atrophy in study eye
- Subretinal hemorrhage that involves the center of the fovea in study eye
- History of vitrectomy surgery, submacular surgery, or other surgical intervention for AMD in study eye
- Prior treatment with Visudyne®, external-beam radiation therapy, or transpupillary thermotherapy in study eye
- Previous intraocular device implantation in study eye
- Previous laser (any type) used for AMD treatment in study eye
- Treatment with anti-VEGF agents other than ranibizumab within 1 month prior to the randomization visit in either eye
- Prior participation in a clinical trial involving anti-VEGF drugs within 6 months prior to the randomization visit, other than ranibizumab in either eye
- CNV due to other causes, such as ocular histoplasmosis, trauma, or pathologic myopia in either eye
- Uncontrolled blood pressure
- History of stroke within the last 3 months prior to informed consent
- Uncontrolled atrial fibrillation within 3 months of informed consent
- History of myocardial infarction within the last 3 months prior to informed consent
- History of other disease, metabolic dysfunction, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of ranibizumab or placement of the Implant and that might affect interpretation of the results of the study or renders the participant at high risk of treatment complications in the opinion of the investigator

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- Current systemic treatment for a confirmed active systemic infection
- Chronic use of oral corticosteroids
- Active cancer within 12 months of randomization
- Previous participation in any non-ocular (systemic) disease studies of investigational drugs within 1 month preceding the informed consent (excluding vitamins and minerals)

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