ForPatients
by Roche

Neovascular Age-related Macular Degeneration

A clinical trial to evaluate maintenance of vision after switching to treatment with an eye implant containing ranibizumab in participants with neovascular age-related macular degeneration

A Study Assessing Corneal Endothelial Cells in Patients With Neovascular Age-related Macular Degeneration Treated With the Port Delivery System With Ranibizumab (PDS)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	NCT04853251 ML43000

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will assess corneal endothelial cells in patients with neovascular age-related macular degeneration (nAMD) treated with Port Delivery System with ranibizumab (PDS) refilled every 24 weeks (Q24W)

Genentech, Inc.
Sponsor

Phase 4
Phase

NCT04853251 ML43000
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=50 Years	No

1. Why is the Belvedere clinical trial needed?

Age-related macular degeneration (AMD) is a condition that causes blurred or reduced central vision in one or both eyes. There are two forms of AMD depending on how the back of the eye (known as the macula) is damaged, ‘dry AMD’ and ‘neovascular AMD’ (also called wet AMD). In wet AMD, a chemical produced by the body called vascular endothelial growth factor (VEGF) causes abnormal blood vessels to be formed in the eye that can leak fluid onto the back of the eye and affect vision.

Wet AMD can be treated by injecting a type of drug called anti-VEGF (e.g. ranibizumab), into the eye (also known as an intravitreal injection). However, many people find anti-VEGF intravitreal injections burdensome, as they are given as often as every 1#2 months. To reduce this burden, a refillable eye implant was designed that continuously releases ranibizumab over time, with refills of ranibizumab approximately every 6 months. This is called the port delivery system with ranibizumab. After testing in previous trials, the port delivery system with ranibizumab is now approved for the treatment of wet AMD.

In this trial, researchers will assess how well vision is maintained in people who switch from a previous anti-VEGF treatment (other than ranibizumab) to the eye implant that contains ranibizumab.

2. How does the Belvedere clinical trial work?

This clinical trial is recruiting people who have a health condition called wet AMD. People can take part if they have previously received treatment with at least three anti-VEGF intravitreal injections other than ranibizumab, within 9 months prior to Day 1 of the clinical trial.

One eye will be chosen as the ‘study eye’, and all participants in this trial will receive the eye implant pre-filled with ranibizumab, in the study eye using a surgical procedure. The eye implant will be refilled with ranibizumab during clinic visits on Weeks 24 and 48. Participants will have approximately 11 in-person clinic visits, and these may last 2#4 hours. These visits are to see how the participant is responding to the treatment and any side effects they may be having. Participants will also have approximately five clinical trial assessments by telephone or video call. Participants’ total time in the clinical trial will be roughly 1 year. Participants are free to stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the Belvedere clinical trial?

The main clinical trial endpoint (the main results that are measured in the trial) is to evaluate the maintenance of vision after treatment in the study eye at Week 40, which is measured using an eye chart at a starting distance of 4 metres.

The other clinical trial endpoints include an assessment of the maintenance of vision in the study eye at Week 40 according to previous intravitreal treatments received, measurement of visual maintenance up to Week 52, and the number and seriousness of any side effects experienced by the participant during the trial.

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 50 years old, have been diagnosed with wet AMD within the past 6#18 months, and have previously been treated with at least three anti-VEGF intravitreal injections other than ranibizumab.

People may not be able to take part in this trial if they have had previous eye surgery (except for cataract surgery if done more than 6 months ago), or received certain treatments, have a history of certain other medical conditions, are pregnant or are planning to soon become pregnant, or are breastfeeding.

5. What treatment will participants be given in this clinical trial?

This is an open-label trial, which means everyone involved, including the participants and the doctors, know which clinical trial treatment is being used. Everyone who joins this clinical trial will receive the eye implant (pre-filled with the clinical trial drug, ranibizumab) in the study eye. This procedure takes around 30 minutes. The eye implant will then be refilled with ranibizumab at Week 24 and Week 48, during a procedure in the clinical trial doctor’s clinic that takes typically less than 15 minutes.

If the treatment is not having the desired effect, participants may receive an extra intravitreal injection of ranibizumab at the clinical trial specified visits (Week 16 and Week 40 or possibly at Week 20 and Week 44).

What does the Belvedere clinical trial look like?

1. Can I take part in this clinical trial?

If the trial is still open to new participants, your doctor will run tests to see if the clinical trial is suitable for you

If you have neovascular age-related macular degeneration and the clinical trial is suitable for you, your doctor will explain the clinical trial and the rights that you have so you can decide if you want to take part

2. What treatment will I be given?

This is an open-label trial, which means everyone involved, including the participants and the doctors, know which clinical trial treatment is being used. Everyone who joins this clinical trial will receive the same clinical trial drug and will undergo the same surgical procedure: one eye will be chosen by the clinical trial doctor and an eye implant (pre-filled with the clinical trial drug, ranibizumab) will be placed into the study eye

Treatment phase (48 weeks)

Following surgical insertion of the eye implant, all participants will receive refills of ranibizumab on Weeks 24 and 48

3. What happens during the clinical trial?

You will have roughly 11 in-person clinic visits and visits may last 2–4 hours. You will also have approximately five clinical trial assessments by telephone or video call

Clinic and phone visits will include checks to see how you are responding to the treatment and any side effects that you may be having

Your total time in the clinical trial will be about 1 year

You can leave this clinical trial at any time and you will not lose access to your regular care

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the clinical trial treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drug (1) and device (2)

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug or device used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

Ranibizumab given via an eye implant

- Participants will be told about the known side effects of the clinical trial drug, ranibizumab, when given with an eye implant device.
- Potential participants will be told about the known side effects of the procedures involved in inserting, filling, refilling and removing (if needed) the eye implant device, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar devices.

Potential benefits associated with the Belvedere clinical trial

Participants' health may or may not continue to improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04853251