ForPatients
by Roche

Age-Related Macular Degeneration Neovascular Age-related Macular Degeneration

A clinical trial in people with wet age-related macular degeneration (wet AMD) which compares (a) ranibizumab delivered by a permanent eye implant with (b) aflibercept delivered by injections into the eye

A Study Of The Effectiveness And Safety Of A 36-Week Refill Regimen For The Port Delivery System With Ranibizumab Vs Aflibercept Treat & Extend In Subjects With Neovascular Age-Related Macular Degeneration

Trial Status	Trial Runs In	Trial Identifier
Withdrawn	6 Countries	NCT05126966 2021-003226-71 MR42410

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 evaluate the effectiveness and safety of a 36-week refill regimen for the Port Delivery System with ranibizumab 100 mg/mL (PDS Q36W) compared with intravitreal injections of aflibercept (2 mg) administered per treat-and-extend (aflibercept T&E) in subjects with neovascular (wet) age-related macular degeneration (nAMD).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT05126966 2021-003226-71 MR42410
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=50 Years	No

How does the DIAGRID clinical trial work?

This clinical trial is recruiting people who have a disease called wet age-related macular degeneration (wet AMD).

Wet AMD is currently treated with anti-vascular endothelial growth factor (anti-VEGF) therapies such as ranibizumab or aflibercept. Anti-VEGF therapy consists of ongoing injections into the affected eye. For example, aflibercept is typically injected once every two months – this can be a burden for patients.

Currently, many doctors use an approach called “treat-and-extend” to give anti-VEGF injections less often while protecting vision at the same time. If the patient’s wet AMD is under control at an injection visit, then the doctor may increase (“extend”) the amount of time to the next injection. If the patient’s wet AMD has worsened, then the doctor may reduce the time to the next injection instead.

The Port Delivery System (PDS) is a new and alternative way to reduce the number of anti-VEGF injections needed. The PDS is a tiny implant that is permanently placed into your eye through the sclera, the white part of your eye. The PDS contains a supply of ranibizumab, which is slowly released into the eye. Every few months, the PDS is refilled with ranibizumab through an outside port. Different refill intervals are being studied.

The purpose of this clinical trial is to compare the effects, good or bad, of PDS with ranibizumab versus afilbercept injections given via treat-and-extend regimen. In this clincal trial, you will get either PDS with ranibizumab or afilbercept injections given via treat-and-extend regimen.

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. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

To be able to take part in this clinical trial, you must:

- be at least 50 years old
- have been diagnosed with wet AMD within the last 9 months
- have received at least three injections into the eye of a standard anti-VEGF treatment for your condition within the last 6 months
- have had your wet AMD improve since starting the anti-VEGF injections (in other words, your vision did not worsen and examination of your retina showed the wet AMD had been controlled since starting the injections)

You must not:

- have any allergy to either ranibizumab or aflibercept
- have certain conditions or previous surgeries to one or both of your eyes

- have certain serious health problems unrelated to your eyes (though other eye conditions, surgeries, or health problems are allowed)
- have taken certain medications

Your doctor will consider your medical history and medications list to see if you can participate in this clinical trial.

You will have further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They 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. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in this clinical trial, women (if they are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Once your clinical trial doctor confirms you are eligible to take part in this trial, you may have one dose of ranibizumab injected into the eye (depending on your treatment history) before you are put into a treatment group. Everyone who joins this clinical trial will be put into one of two groups randomly (like flipping a coin) and have either:

- A PDS with ranibizumab device permanently implanted on Day 1 and then refilled at Week 36 and Week 72. There is a small chance that you will need one or two additional injections of ranibizumab into the eye before the refills planned at Week 36 and Week 72
- OR aflibercept given as an injection into the eye on Day 1, then again at Week 4. After Week 4, your doctor will use treat-and-extend to decide when your next aflibercept injection will be. The maximum time between injections will be 12 weeks and the minimum time between injections will be 4 weeks

You will receive these treatments until Week 80 (roughly one and a half years after starting the clinical trial). You will have an equal chance of being placed in either group.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment PDS with ranibizumab OR aflibercept injections following the treat-and-extend regimen for around a year and a half. You are free to stop this treatment at any time. After starting treatment, you will still be seen regularly by the clinical trial doctor.

If you receive PDS with ranibizumab, you will be seen on Day 1, Day 2, Day 7, Week 4, then every 4 to 8 weeks until your first refill at Week 36. After your first refill, you will be seen every 4 to 12 weeks depending on what your clinical trial doctor feels is most suitable.

If you receive aflibercept injections you will be seen every 4 to 12 weeks depending on what your clinical trial doctor feels is most suitable, according to the treat-and-extend regimen.

Whichever treatment you receive, these clinic visits will include checks to see how you are responding to the treatment and any side effects that you may be having. These checks may include:

- Questionnaires on how well your eyes are working
- Eye tests and examinations
- Photographs of your eyes

You will also occasionally receive follow-up calls to check on how you are doing. If you experience any side effects or injury during the trial, your clinical trial doctor will explain your options and discuss a plan for further treatment with you.

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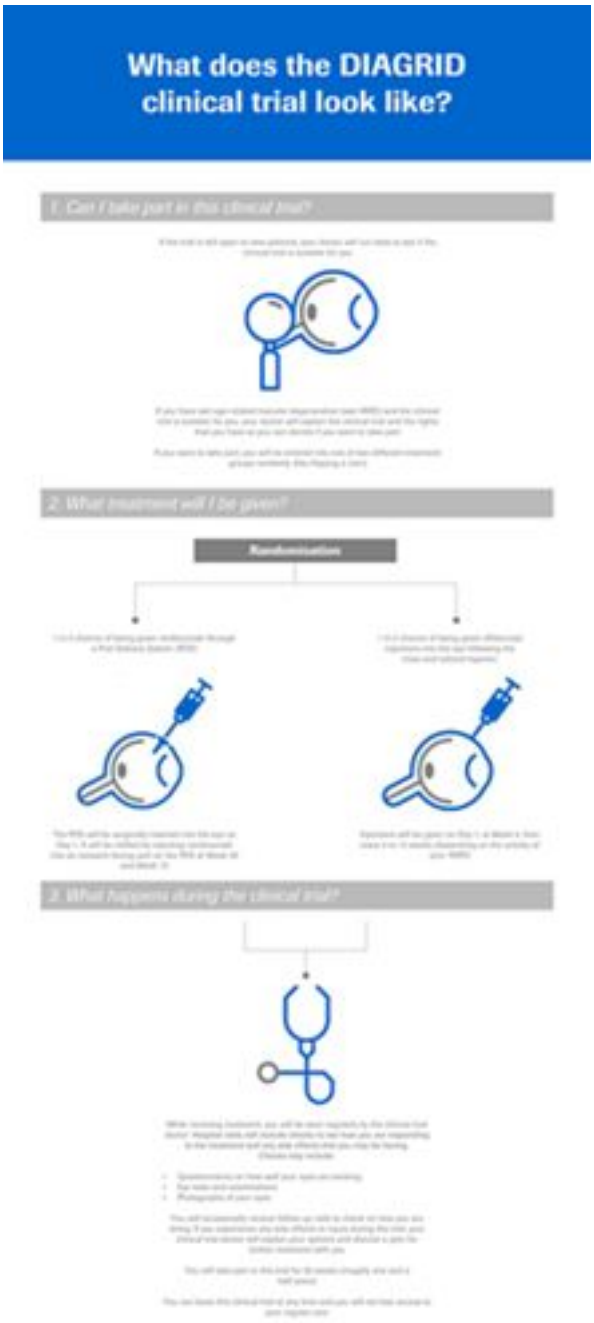

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What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05126966

Trial-identifier: NCT05126966