LAY CLINICAL TRIAL DESCRIPTION / PROTOCOL SYNOPSIS in LAY LANGUAGE

Roche Trial Number / Trial acronym (if available):
GR40549 / Portal Iridex

National Clinical Trial Number / EU Clinical Trial Number:
NCT03683251 / To be confirmed

Trial title: Transscleral photocoagulation laser study in association with study GR40549: a multicenter, open-label extension study to evaluate the long-term safety and tolerability of the port delivery system with ranibizumab in patients with neovascular age-related macular degeneration (Portal)

Lay study title:

A study to find out how safe it is to use a different type of laser (cleared for use by the Food and Drug Administration) during surgery to insert an eye implant that releases medicine for people with wet age-related macular degeneration (nAMD)

1. Why is this study needed?

Neovascular (or wet) age-related macular degeneration (nAMD) is a medical condition where unhealthy blood vessels grow in the central area at the back of the eye. These vessels cause swelling and bleeding at the back of the eye. This can lead to vision loss.
nAMD can be treated with anti-VEGF drugs like ranibizumab, which are injected into the eye. These injections are needed as often as every 1 to 2 months. To reduce the rate of injections, a refillable device that is put into the eye (an eye implant) was designed to slowly releases ranibizumab over time. This implant, known as the Port Delivery System with ranibizumab, only needs to be refilled with ranibizumab about every 6 months. After testing in previous studies, the eye implant was approved by the health authority in the United States (the U.S. Food and Drug Administration [FDA]) for the treatment of nAMD.
The eye implant is put into the eye during surgery. A laser is used during this procedure to reduce bleeding in the eye during and after surgery. A different type of laser (that has been cleared for use by the FDA) may also prevent bleeding inside the gel-like substance inside the eye during and after surgery. This different type of laser may simplify the surgery.
This study aims to test if the different type of laser simplifies the surgery procedure when the eye implant is put into the eye, and how safe it is to use this different laser

2. Who can take part in the study?

People of at least 50 years of age can take part in the study if they have been diagnosed with nAMD within the past 2 years and have responded well to at least 2 anti-VEGF eye injections within 6 months of starting the study.
People may not be able to take part in this study if they have had an eye implant or laser treatment for nAMD before or if they are already taking part in another eye implant study. People who have a history of certain medical conditions or other eye diseases or who are taking certain treatments may not join the study. People who are pregnant, currently breastfeeding, or are planning to become pregnant during the study or within 1 year of their eye implant being refilled, also cannot take part.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 3 to 5 weeks after a person's last injection of anti-VEGF into the eye. This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.
Everyone who joins this study will be given:

- Surgery to put the eye implant in the eye using the different type of laser
- Ranibizumab refills as injections into eye implant every 6 months

If ranibizumab treatment is not working as well as expected, the study doctor may give extra ranibizumab as an injection into the eye 1 and 2 months before the next eye implant refill is due, as needed.During this study, participants will visit the study doctor twice in the week after the eye implant is implanted, then every month for 6 months. After this, visits will be every 2 months. The study doctor will see how well the treatment is working and any unwanted effects participants may have. The study doctor will also contact participants a few days after each eye implant refill to check on their wellbeing. If a participant or the study doctor choose to stop study treatment, participants will be asked to stay in the study and complete all visits.
Participants will have a final visit 2 months after their final refill or about 2 years after the eye implant was put into the eye. If the participant leaves the study early, they will have a final visit 1 month after their previous visit or 3 months after the eye implant was put into the eye. During these visits, the study doctor will check on the participant's wellbeing and discuss whether the eye implant should be removed from the eye. If the eye implant is removed, participants will have 2 follow-up visits that week, then monthly visits for 2 months. Total time of participation in the study will be about 2 years. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main result measured in the study is the number of participants that have bleeding that lasts for more than 1 month after the eye implant.
Other key results measured in the study include:

- The number and seriousness of unwanted effects
- The amount of time it takes for any bleeding inside the eye to stop after surgery
- The number of participants with severe bleeding inside the eye, and changes in the amount of blood in the eye over time
- How often participants need surgery to remove the gel-like substance inside the eye (called a 'vitrectomy')
- Change in eyesight when using glasses or contact lenses and the number of participants with certain levels of changes
- Changes in the thickness of the eye layers

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.
It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicine, device, or procedures
Participants may have unwanted effects of the medicine, devices, or procedures used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular checks for any unwanted effects.

Ranibizumab
Participants will be told about the known unwanted effects of ranibizumab given using the eye implant or as injections into the eye, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include pain or discomfort in the head, feeling that there is something in your eye, eye pain or irritation.
The study medicine(s) may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.

Port Delivery System with Ranibizumab
Participants will be told about any known unwanted effects of the eye implant, and where relevant, also potential unwanted effects based on human and laboratory studies or knowledge of similar devices. The eye implant will be put into the eye under local anaesthetic (a medicine that numbs a specific area of the body, preventing the sensation of pain in that area). Participants will be told about any known unwanted effects of the procedures involved in inserting, filling, refilling and removing (if needed) the eye implant, and, where relevant, potential unwanted effects based on human and laboratory studies or knowledge of similar procedures.