ForPatients
by Roche

Diabetic Retinopathy

A clinical trial to compare different doses of RG7774 with a placebo in people with moderate and severe stages of non-proliferative diabetic retinopathy (NPDR), an eye disease that develops due to diabetes.

A Study to Investigate the Efficacy and Safety of RG7774 in Patients With Diabetes Mellitus Type 1 or Type 2 With Treatment-Naive Diabetic Retinopathy (CANBERRA)

Trial Status	Trial Runs In	Trial Identifier
Completed	7 Countries	NCT04265261 2019-002067-10 BP41321

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

Trial Summary:

The study's main purpose is to asses the safety, tolerability, and effect of oral administration of RG7774 on the severity of diabetic retinopathy (DR) in participants with moderately severe to severe non-proliferative diabetic retinopathy (NPDR) and good vision.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04265261 2019-002067-10 BP41321
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

Why is the CANBERRA clinical trial needed?
In people with diabetes, high blood sugar levels can damage blood vessels in the retina (back of the eye). This condition, called diabetic retinopathy (DR), often worsens over time and can lead to serious problems with vision. Current treatment options include laser, microsurgery (called vitrectomy) and medications injected into the eye. However, these treatments are known to be invasive and are only used if there are already serious vision problems.

We want to learn if our investigational drug RG7774 is safe and how it affects disease severity, progression and vision.

How does the CANBERRA clinical trial work? This clinical trial is recruiting people who have moderate to severe stages of non-proliferative diabetic retinopathy (NPDR), an eye disease that develops due to diabetes. People can take part if they have good vision and have not yet received any treatment for this disease in at least one eye.

Our investigational drug, RG7774, has been developed specifically for oral administration and is administered as a tablet once daily.

The purpose of this study is to test the safety and efficacy of RG7774 at different doses and to find out what effects, good or bad, RG7774 has on the eye specifically, but also on the entire body. Patients who take part in this clinical trial will receive either RG7774 or a placebo (no active drug).

How often will I be seen in follow-up appointments, and for how long? The CANBERRA study will last about one year. You are free to stop this treatment at any time. Unless you leave the study early for any reason, you will have some site visits within one year, which include a screening visit. The purpose of these visits is that we can monitor your eye and general health and see how you are responding to your treatment. If you experience any side effects or injury during the study, your study doctor will explain your options and discuss with you a plan for further treatment. Participants are free to stop trial treatment and leave the clinical trial at any time.

What are the main endpoints of the CANBERRA clinical trial? Clinical trial endpoints are pre-defined and established to measure how participants are doing within the study objectively. The main results measured in the study showing treatment effect are referred to as the primary endpoints. Secondary endpoints provide supportive information about a medicine’s effect on the primary endpoint. If you have further questions about endpoints, please talk to your doctor.

The primary endpoints for the CANBERRA study are:

- When your eye doctor examines your eye, the damage from the diabetes can be graded according to an internationally recognized grading scale, called the Early Treatment of Diabetic Retinopathy Scale - Diabetic Retinopathy Severity Scale (ETDRS-DRSS). One of the primary endpoints of the study is to measure at week 36 whether RG7774 can reverse the severity of this grading by at least 2 grades when compared to the start of the study.
- Another endpoint is to monitor for the number and severity of side effects due to the medication from the start of the study to its completion at 52 weeks (1 year).

The other clinical trial endpoints are:

- The percentage of participants that demonstrate the progression to vision-threatening retinal disease. If this happens, the examining doctor notes the presence of
    - anterior segment neovascularization (ASNV) which are abnormal blood vessel growth on the colored part of the eye called the iris
    - abnormal blood vessels growing on the surface of the retina, called (proliferative diabetic retinopathy (PDR))
    - the development or worsening of swelling of the centre of the retina (macula), called diabetic macular edema (DME).
- The change in best corrected visual acuity (BCVA) from the beginning of the study compared to week 36 of the study. BCVA is the best possible vision your eyesight can be improved to with a formal eyesight test.

Who can take part in this clinical trial? You may be able to take part in this study if you:

- Are 18 years or older
- Have good vision and a specific grade of diabetic retinopathy (non-proliferative diabetic retinopathy) for which you have not previously received treatment for
- Have diabetes mellitus type 1 or type 2 for which you take an oral or injectable medication
- Have a blood glucose level (HbA1c) #12%
- Have health checks and tests and answer questions to confirm you can take part in the study.

If you think this clinical trial may be suitable for you and would like to participate, please talk to your doctor. If your doctor thinks that you might be able to take part, 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. You can also find the clinical trial locations on this page.

At the clinical trial site you will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Before starting, you will be told about any risks and benefits of taking part in the trial.

What treatment will participants be given in this clinical trial? If you agree to participate and screening tests show that you are eligible, you will be assigned by chance or randomized to one of three study groups. Participants in each group will take one of the following by mouth on a once a day basis for 36 weeks (approximately 9 months).

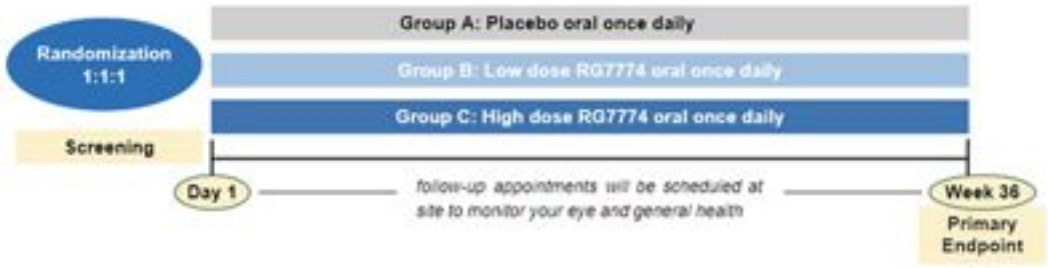
- A placebo (no active drug) oral once daily
- A low dose of RG7774 oral once daily
- A high dose of RG7774 oral once daily

You will have a 1:3 chance of receiving placebo, or RG7774 at a low dose, or the high dose of RG7774.

The doses that will be tested in the study were found to be safe and well tolerated in earlier clinical trials.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given a substance with no active ingredients (known as a ‘placebo’) but which will look like the drug being tested. Comparing results from the different groups helps the researchers know whether any changes seen are a result of the drug or occurring by chance.

This is a double-masked trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This approach helps to prevent bias and expectations about what will happen. However, the participant’s clinical trial doctor can readily find out which group the participant is in, if their safety is at risk.



Are there any risks or benefits in taking part in this clinical trial? The safety or effectiveness of the experimental 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 at the outset 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 (this is a document that provides people with all 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 health care 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
Participants may have side effects (an unwanted effect of a drug or medical treatment) from our investigational drug, RG7774 used in this clinical trial. Side effects can be mild to severe and can vary from person to person.

RG7774

Potential participants will be told about the known side effects of RG7774, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

RG7774 and placebo have been developed specifically for oral administration. Participants will be told about any known side effects of systemic administration.

Potential benefits associated with the clinical trial Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have similar diabetes related eye conditions 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/NCT04265261?term=the+canberra+study&draw=2&rank=1