ForPatients
by Roche

Primary IgA Nephropathy

A clinical trial to see how well RO7434656 works compared with placebo in people with primary IgA nephropathy who are at high risk of their kidney disease getting worse

A Study to Evaluate the Efficacy and Safety of RO7434656 in Participants With Primary Immunoglobulin A (IgA) Nephropathy at High Risk of Progression

Trial Status	Trial Runs In	Trial Identifier
Recruiting	21 Countries	NCT05797610 2022-502102-32-00 WA43966

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 purpose of this study is to evaluate the efficacy, safety, and pharmacokinetics of RO7434656, a novel Antisense Oligonucleotide (ASO) therapy in participants with primary IgA nephropathy (IgAN) who are at high risk of progressive kidney disease despite optimized supportive care.

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

NCT05797610 2022-502102-32-00 WA43966
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the WA43966 clinical trial needed?

Primary IgA nephropathy (IgAN) is a disease where the immune system attacks healthy cells in the kidneys by mistake. In healthy individuals, the kidneys have the function of filtering blood to remove waste and control the body's fluid levels. One of the roles of the immune system is to create antibodies to help destroy foreign objects (e.g. bacteria and viruses), protecting your body against infection. However, in primary IgAN, the body produces some incorrect antibodies that end up causing high blood pressure, inflammation

and long-term kidney damage. Standard treatment for primary IgAN includes drugs to control blood pressure and may include drugs to lower the activity of the immune system. These can cause unacceptable side effects, and there is no cure for primary IgAN. If not treated, IgAN causes kidney failure - a kidney transplant or dialysis (when blood is cleaned, usually by a machine) is needed to live. A drug called RO7434656 may reduce the levels of inflammation and protect the kidneys from long-term damage in people with primary IgAN. RO7434656 is an experimental drug, which means health authorities have not approved it yet for treating IgAN. This clinical trial aims to compare the effects, good or bad, of RO7434656 versus placebo in people with primary IgAN who are at high risk of their kidney disease getting worse.

2. How does the WA43966 clinical trial work?

This clinical trial is recruiting people with primary IgAN. People can take part if there is a high risk of worsening kidney disease. People who take part in this clinical trial (participants) will be given the clinical trial treatment RO7434656 OR placebo for about 2 years. The clinical trial doctor will see them approximately every 2–12 weeks (typically every 12 weeks after the first 6 months). These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The total time in the clinical trial will be approximately 2 years, or longer if participants choose to continue treatment after 2 years (see section 5 below). After the last dose of clinical trial treatment, participants will be seen at a follow-up visit. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the WA43966 clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the drug has worked) is the level of protein found in urine at Week 37 compared with the start of the trial (which indicates the level of kidney damage). The other clinical trial endpoints include:

- How well the kidneys are working after 2 years of treatment
- How much time passes before kidney failure
- How tired participants feel at 2 years compared with the start of the trial
- The number and seriousness of any side effects
- How the body processes RO7434656

4. Who can take part in this clinical trial?

People can take part in this trial if they are over 18 years old, have high amounts of protein in their urine and have received certain treatments for primary IgAN for at least 3 months before the trial.

People may not be able to take part in this trial if they have:

- Received certain treatments, such as steroids or herbal therapies, within 3 months before the trial
- Certain other medical conditions such as very low kidney function, severe kidney disease, heart disease, diabetes, certain infections, or if they are women who are pregnant or breastfeeding or are planning to become pregnant during the trial or within 3 months after the final dose of RO7434656
- Refused to get vaccinations against certain bacterial infections

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

Everyone will be given **RO7434656** OR **placebo** as an injection under the skin on Weeks 1, 3 and 5, then every 4 weeks up to 2 years of treatment. Participants will have an equal chance of being placed in either group. This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given a substance with no active ingredients (also known as a 'placebo'); it looks like the drug being tested but does not contain any real medicine. Comparing results from the different groups helps the researchers know whether any changes seen result from the drug or occur by chance. This is a double-blinded 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 find out which group the participant is in, if their safety is at risk. After 2 years of clinical trial treatment, participants may continue to receive the blinded treatment (RO7434656 or placebo). In certain situations, the clinical trial doctor may give participants RO7434656 instead of placebo if they believe a participant will benefit. In this case, the participant and the doctor will know they are being given RO7434656. Treatment may continue until the last participant to join the trial has finished it. Participants or caregivers may give the injections themselves at home. Participants will be given specific vaccinations for Neisseria meningitidis, Streptococcus pneumoniae and Haemophilus influenzae according to local guidelines to protect them from bacterial infections.

6. 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. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate 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. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs

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

threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly. Participants will be told about the known side effects of **RO7434656** (such as increased risk of infection) and **placebo**, and possible side effects based on human and laboratory studies or knowledge of similar drugs. **RO7434656** and **placebo** will be given as an injection under the skin (subcutaneous injection). Participants will be told about any known side effects of subcutaneous injection.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.