

IMAgINATION

A global clinical study for people with primary IgA nephropathy (IgAN)

The search for a new treatment begins with you!



The image features a solid red background. On the right side, there are several overlapping, semi-transparent white circles of varying sizes, creating a decorative pattern. The word "IMAgINATION" is centered in the middle of the page in a white, sans-serif font. The letter 'g' is lowercase and has a distinctive, rounded shape.

IMAgINATION

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What is IMAGINATION?

IMAGINATION (WA43966) is a global clinical study to test a potential new treatment for people with primary IgA nephropathy (IgAN).

More than 400 adults from around the world will take part in IMAGINATION. This study will test how well the study drug (RO7434656) works, and how safe it is.

About IgA nephropathy (IgAN)

IgAN is a rare autoimmune disease. In people with IgAN, an uncommon form of the protein IgA1 builds up in the kidneys. This causes the kidneys to stop working properly, and allows blood and protein to leak into the urine. Over time this can lead to serious kidney problems, and even kidney failure.

Although there is no cure for IgAN, treatments are available to manage symptoms and slow disease progression. However, an unmet need remains for people whose IgAN continues to progress despite these treatments.

Common symptoms of IgAN



Blood or protein
in the urine



High blood pressure



Swelling of the
ankles or face
(or other parts
of the body)



Fatigue

What treatment could I receive?

If you choose to join the study, then you will be randomly selected to receive either the potential new treatment (RO7434656) or a placebo. You will have an equal chance of receiving each treatment – like tossing a coin. The study is double-blinded, so neither you nor your study team will know which treatment you are receiving.

If you are taking any blood pressure therapies or statins, then you can keep taking them alongside your study medications.

If you choose to join the study, you will be closely monitored and have full access to your local study team, ensuring a high level of care throughout your time in the study.



What is a placebo?

A placebo is something that looks like a drug but has no active ingredient or medicine

What is RO7434656?

RO7434656 (also known as sefaxersen) is the investigational drug, which means it has not yet been approved by health authorities. It works in a unique way, by targeting parts of the immune system that damage vessels in the kidneys. This means that it has the potential to stop the kidney damage caused by IgAN.

Am I eligible?

You may be eligible to join the IMAGINATION study if you:



Are at least
18 years old



Have a confirmed
diagnosis of IgAN

If you are eligible and interested in participating, your study doctor will talk through the study with you and answer your questions. You will then be asked to read and sign an **Informed Consent Form (ICF)**.

Joining a clinical study is completely voluntary. It is an important and personal decision, so please take time to make sure it is the right choice for you.

Informed consent form (ICF)



Signing the ICF means that you understand what the study involves, and you agree to take part. Please note, you can change your mind at any time.

What happens if I join the study?

1. Screening – up to 3 months

After signing your ICF, you will go into **Screening**. This is when your study doctor will do tests to make sure you qualify for the study.

These will include:



Background information and medical history



Physical examination



ECG (to measure your heart activity)



Taking blood and urine samples



Pregnancy test (if relevant)



Tests for specific conditions



You will only need a kidney biopsy to confirm your diagnosis of primary IgAN if you have not had one in the past 10 years

2. Treatment – about 2 years

If you qualify then you will be randomly placed into a treatment group – for placebo or RO7434656. The treatments will be given by needle injection under the skin.

How often are study visits?

Visits are every 2 weeks for the first month, then once a month. If allowed in your country, you may be eligible to administer the drug at home and attend visits at your study center less frequently.

How long do visits take?

Most visits will last 1 to 2 hours, but a few may last up to 10 hours.

Where will they happen?

Some visits need to be at the study center, but you may be able to do some visits from home – please speak with your study doctor to find out more.

What happens during visits?

It varies between longer and shorter visits, but you will have similar tests to screening. At some visits you will also need to:



Bring a 24-hour urine sample



Complete questionnaires about your health

Optional open-label treatment – up to the end of the study

At the end of the 2-year treatment period, you may be able to receive open-label treatment with R07434656. This will be based on your study doctor's assessment of how you have responded to treatment.



Open-label means that you and your local study team know that you are receiving R07434656.

Safety follow-up – 3 months

At the end of the study, you will have two follow-up visits: one around 1 month after your final treatment and another around 3 months after your final treatment. This is to check your health and well-being after stopping treatment.

What are my responsibilities as a participant?

✓ Do	✗ Do not
Attend all study visits	Take part in other clinical studies at the same time
Complete all procedures and tests	Take any medications your study doctor asks you to avoid
Tell your personal doctor and family that you are taking part in this study	
Always carry your Subject ID card	
Use reliable birth control during the study	
Tell your study doctor of any changes to your health or medications	

What are the benefits and risks?

Possible benefits

Taking part in a clinical study will help doctors learn more about IgAN and could help others in the future, but there is no guarantee it will improve your health.

- ✓ Regular health check-ups and close medical monitoring
- ✓ Study treatments and related tests at no cost
- ✓ Possible improvements in your health or condition
- ✓ You will be helping in the search for new and better treatments for your condition
- ✓ If you qualify, you may be able to continue receiving the study drug after the end of the 2-year treatment period

Potential risks

There are risks to participating in any clinical study. You may experience side effects from study treatments or tests. These can vary between mild and severe for different people.

- You may not receive the new treatment and could be given a placebo
- You may have side effects from study treatment
- You need to make time for health check-ups and study assessments
- Your health may not improve or could even get worse while you are in the study

Please speak to your study doctor to understand more about the risks from study treatment. More information is available in the ICF. Your health is important to us and will be monitored throughout the study. If you have any side effects, please let your study doctor know immediately.

Costs

- You will not have to pay for any study treatments or tests
- You will be reimbursed for any reasonable study-related costs (such as transport)

If you are injured because you took part in IMAGINATION, please contact your study doctor immediately. They will explain your options and where you can receive treatment.



I'm excited to take part!

What happens next?

If you or a loved one want to find out more about IMAGINATION, please speak with your local study team:

Contact name:

Clinic name:

Clinic address:

Telephone:

Email:



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