NATIONAL KIDNEY FOUNDATION®

CLINICAL TRIAL OVERVIEW FOR PEOPLE WITH IgAN

A clinical trial tests new treatments for efficacy and safety. Led by doctors, these studies help find better ways to prevent, diagnose, or treat diseases like IgA Nephropathy (IgAN).

What is IgAN?

IgA nephropathy (IgAN) is a type of kidney disease where antibodies build up in your kidneys and cause damage to your glomeruli (small filters inside your kidneys). Antibodies are a type of protein made by your immune system to protect against things like bacteria and viruses.

What is a clinical trial?

A clinical trial is a research study that looks at how well a new treatment works in people. The treatment may be a drug, medical procedure, medical device, or even a lifestyle change. A clinical trial also makes sure the new treatment is safe, well tolerated, and does not cause harm or serious side effects in most people.

In short, a clinical trial helps to answer two important questions:

- **Does the new treatment work in humans?** If so, how well does it work? Is it better or the same as treatments that are currently available? If it is the same, does it have fewer side effects than other treatments? Does it help people who have not responded to other treatments?
- **Is the new treatment safe?** No treatment is completely safe for everyone. However, a clinical trial helps make sure the benefits outweigh the possible risks for most people.

Who conducts clinical trials?

Each clinical trial is led by a principal investigator, who is usually a medical doctor. In addition, there is often a team of doctors, nurses, social workers, and other health professionals who will work directly with you and provide your medical care. To cover the costs involved, a study must also have financial support (funding). This funding may come from a drug company (pharmaceutical), university medical center, government agency, or other organization. The group that provides funding is usually referred to as the "sponsor."

Why are clinical studies divided into phases?

Each phase has a different goal or certain questions it is trying to answer.

Phase 1	What is the best dosage with the fewest side effects?
Phase 2	Does this work, and is it well-tolerated by most people?
Phase 3	Is this treatment more effective than others currently on the market?
Phase 4	How does this affect special populations, for example, those with kidney disease?

What should I expect during a clinical trial?

Participating in a clinical trial can include the following steps.

- **Screening:** If you are interested in a trial, your care team will review your medical history and run tests to see if you meet the study's eligibility requirements.
- **Informed Consent:** Before joining, researchers will explain all details of the study, including potential risks and benefits, so you can make an informed choice.
- **Treatment & Monitoring:** You will receive the study medication (or a control/placebo, depending on the study design) and attend regular check-ups to track your kidney health and overall well-being.
- **Completion:** After the trial concludes, your doctors will discuss your ongoing care options.

Why are clinical studies needed?

Clinical trials try to find better ways to prevent, screen for, diagnose, or treat diseases and other health problems. Without them, we would not have new treatments or other advances in health and medicine.

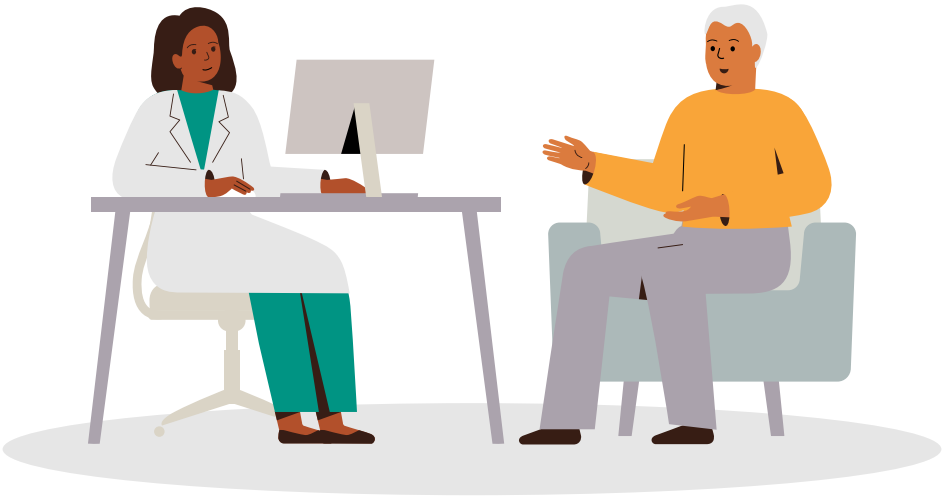
What are the goals of clinical trials for IgA Nephropathy (IgAN)?

IgAN clinical trials evaluate new treatments that aim to slow disease progression, reduce proteinuria (protein in the urine), and protect kidney function. Researchers are constantly working to develop newer, more targeted therapies that can stop the underlying immune response and better protect your kidneys. Clinical trials have tested disease-modifying drugs that target specific pathways involved in IgAN.

Questions to ask

If you are thinking about joining a clinical trial, here are some questions to start your conversation with a healthcare professional:

- Is a clinical trial right for me?
- Can I participate for any current IgAN clinical trials?
- What is the main goal of this clinical trial (e.g., safety, effectiveness)?
- What treatments will I receive, and is there a chance I might receive a placebo? If I end up receiving a placebo, can I still get the treatment afterwards?
- How many extra medical visits, blood tests, or biopsies will be needed?
- Will my travel or medical expenses be covered by the study?



For more information, contact the National Kidney Foundation

Toll-free help line: 855.NKF.CARES or email: nkfcares@kidney.org

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