

If you are undergoing a kidney transplant, the AWAKE Study could help improve your outcome after transplant. Talk to your doctor to learn more.

What You Should Know About Clinical Research Studies

Clinical research studies aim to answer specific questions about how medicines work in the volunteers who take them and to get new medicines and treatments approved for everybody's use. You should feel fully informed about what to expect from participation in a clinical research study.

Researchers use clinical research studies to:

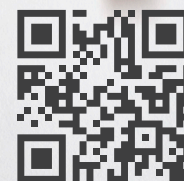
- Answer specific health questions
- Learn about the safety and effectiveness of investigational medications
- Help find new ways of using approved medications

Regulations and policies have been developed to help protect the rights, safety, and well-being of people who take part in clinical research studies and to help ensure that these studies are conducted according to strict scientific and ethical principles. Before a clinical research study can begin, an institutional review board (IRB) or ethics committee (EC) must review and approve the study.

Participation in any clinical research study is completely voluntary, and you may withdraw from a clinical research study at any time for any reason. Before participating in a clinical research study, it is important to weigh the potential risks and benefits of participation. The study team will inform you of the potential risks and benefits of study participation, as well as possible side effects. To make an informed decision, gather as much information as possible and talk to your healthcare providers about any questions you may have.

During the study, you will work with a study team that may include study doctors, study nurses, and other research staff.

Thank you for considering the AWAKE Study. For more information on the study, talk to your doctor or contact the sites listed here: bit.ly/awakestudy.



How Do You Picture
Life After Your
Kidney Transplant?





About the AWAKE Study

The purpose of the AWAKE Study is to find out how safe an investigational medication is and how well it works to help improve outcomes of adults who are undergoing a kidney transplant. This study aims to prevent individuals from developing a potentially serious complication, known as delayed graft function (DGF), after their transplant. Researchers believe the investigational medication being studied may help prevent DGF so that the new kidney can “wake up” and start working.

Participants will be assigned at random to receive either the investigational medication or the placebo. A placebo is a substance that looks just like the investigational medication but does not have any medicine.

The assigned study treatment will be given once as an intravenous (IV) infusion.

All participants will get standard-of-care treatment for their kidney transplant and have their health monitored throughout the study.

The AWAKE Study will last about one year with at least 16 visits, and it consists of these periods:

- **Screening (up to seven days and at least 24 hours before transplant):** Determines if interested individuals can join the study.
- **Transplant:** Participants will get their assigned study treatment up to one day before their transplant. Then, they will receive their transplant as regularly scheduled.
- **Primary Evaluation Period (30 days after transplant):** Participants will be hospitalized for at least four days after their transplant. For 30 days after their transplant, participants will be monitored for their health.
- **Long-Term Follow-Up (under a year):** The study team will continue to check on participants' health.

Throughout the study, participants will have physical examinations, blood and urine sample collections, and questionnaires about how they are feeling. These tests, along with the assigned study treatment, standard-of-care treatments, and the ongoing monitoring of a participant's health, will be provided at no cost. Insurance is not needed to join this study. Compensation and travel reimbursement may be available.

Who Can Participate?

Those eligible to receive a kidney transplant may join the AWAKE Study if they:

- Are 18 years or older
- Have a diagnosis of dialysis-dependent end-stage kidney disease (ESKD)
- Have undergone at least one year of dialysis treatment

There are additional requirements, which the study team will discuss with interested individuals. Some visits may be done at a participant's home in combination with a phone call or telemedicine appointment.

Reducing After-Transplant Complications

When an individual receives a kidney transplant, there is a chance the new kidney does not immediately start working or does not work at all. This condition is known as delayed graft function (DGF). When the kidney does not work within five to seven days after transplant, dialysis may be needed until the kidney starts working.

Dialysis can result in low blood pressure, blood clotting, and long periods of hospitalization. The investigational medication will try to prevent DGF so that the new kidney can “wake up” and immediately work after transplant, thus removing the need for dialysis.

Care Partner Support

Care partners play an important role in the lives of individuals undergoing a kidney transplant. Participation in a clinical research study can also be overwhelming for a participant. A support system, especially a trusted care partner, is critical during this time. Throughout the AWAKE Study, care partners are a vital source of encouragement and emotional support for participants.



Alexion is committed to designing clinical programs with equity at the forefront. We are dedicated to continuing to work to improve participant diversity in clinical studies to mirror the real-world disease population. Our goal is to shape clinical study diversity policies of the future while delivering for patients today.