



AWAKE Study Overview

Study Purpose

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 18 years or older 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.

Study Participation

Participation in this study will last about one year with at least 16 visits. This study is enrolling approximately 450 adult transplant recipients across approximately 18 countries.

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

About the AWAKE Study

- This study will compare the investigational medication to a placebo. A placebo is a substance that looks just like the investigational medication but does not have any medicine.
- Participants will be assigned at random to receive either the investigational medication or the placebo. The assigned study treatment will be given only once as an intravenous (IV) infusion.
- Neither participants nor the study team will know which treatment option has been assigned, but in case of an emergency, the study team can quickly find out.
- All participants will get standard-of-care treatment for their transplant and will have their health monitored throughout the study.
- Some visits may be done at a participant's home in combination with a phone call or telemedicine appointment.

Parts of the Study



Screening: Interested individuals will be evaluated up to seven days and at least 24 hours before their kidney transplant to see if they can join the study.



Transplant: If an individual decides to join the study, they will get their assigned study treatment up to one day before their kidney transplant. Then, they will receive their transplant as regularly scheduled.



Primary Evaluation Period: Participants will be hospitalized for at least four days after their transplant. For 30 days after the transplant, participants will be monitored for their health.



Long-Term Follow-Up: For a little 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. Compensation and travel reimbursement may be available.

The Goal of This Study

The primary goal of this study is to avoid the chance of the kidney not immediately working or never working at all after a transplant. If a newly transplanted kidney does not work after five to seven days, then dialysis is needed until the kidney starts working. The study will try to prevent DGF so that the new kidney can “wake up” and immediately work after transplant.

Thank you for your interest in the AWAKE Study. For more details on eligibility or to learn more information, please talk to your doctor or contact the sites listed here: bit.ly/awakestudy.

