

PARTICIPATING IN A CLINICAL TRIAL

A clinical trial is a research study designed to test a potential improvement in current treatment or obtain information on a new treatment. A research study helps doctors:

- understand whether an investigational medicine or investigational medical device may help treat certain conditions
- learn about the safety and effectiveness of an investigational medicine or investigational medical device
- find new ways to prevent, diagnose, and treat diseases
- study ways to improve the quality of life of individuals living with a chronic condition

All patients who participate in clinical trials are volunteers and may withdraw from the trial at anytime.

The decision to take part in a clinical trial belongs to you. Your doctor and the research team will provide you with any additional information you may need to make this decision. Should you decide to participate in this trial, the research team will be available for your support throughout the trial.

ADDITIONAL INFORMATION

Websites of Interest

www.humacyte.com/HAV-ACCESS/patients

www.humacyte.com

www.clinicaltrials.gov

Contact Information

STUDY PHYSICIAN:

Name

Phone

Email

STUDY COORDINATOR:

Name

Phone

Email



The HAV-ACCESS Study Clinical Trial

for patients with end-stage renal disease (ESRD) who need long-term hemodialysis



The HAV-ACCESS Research Study

The purpose of this Phase 3 clinical trial is to help doctors learn whether a new investigational graft called a human acellular vessel (HAV) works better than an arteriovenous fistula (AVF) for hemodialysis access.



WHAT IS THE HAV?

The HAV is a graft that has been made in a laboratory. Grafts are usually made of a plastic called ePTFE (expanded polytetrafluorethylene). The HAV is grown from smooth muscle cells that were obtained from an organ donor. The donors have been fully tested to ensure that they do not have any infections that could affect you. The cells that form the HAV are a normal part of human blood vessels. As the cells grow, they produce proteins, such as collagen, which create the HAV. When the HAV is fully formed, the donor cells are removed so the HAV itself no longer contains any cells from the organ donor.

CAN I TAKE PART IN THE TRIAL?

You may be able to participate in the HAV-ACCESS research study if you*:

- are 18 years of age or older
- have ESRD
- are receiving hemodialysis through a dialysis catheter
- are a candidate for study hemodialysis access creation through an AVF or implantation of an autologous arteriovenous graft
- plan on receiving hemodialysis at a dialysis center for at least the first 6 months after the creation of hemodialysis access
- are a candidate for implantation of a straight or looped graft in either the forearm or upper arm

**Other inclusion and exclusion criteria will apply.*

HOW DOES THE HAV WORK?

The HAV is a graft that is surgically placed into your arm. Early studies suggest that your own cells may move into the HAV and grow, so that it becomes more like a natural blood vessel. After the HAV is surgically implanted, it is typically ready to be used for dialysis in about four weeks.

WHAT IS THE LENGTH OF THE STUDY?

You may be in the HAV-ACCESS research study for as long as 5 years. The length of time that you will be in the study may depend on the type of hemodialysis access you receive and if you are still using it for dialysis after the 2-year study period during part 1.