Participating in a Clinical Trial

You have been given this brochure because your doctor believes you are a candidate for participating in the HAV-ACCESS 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. Generally, without clinical trials new drugs and treatments could not be approved by the Food and Drug Administration (FDA) and fewer medical advances would be made.

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

Web sites of interest

http://www.humacyte.com/HAV-ACCESS/patients/

www.humacyte.com

www.clinicaltrials.gov

Contact Information

Study Physician:

Dr. Roy Fujitani

Professor of Clinical Surgery

Division of Vascular and Endovascular Surgery

Phone # 714-456-5453

Study Coordinator:

George Kopchok

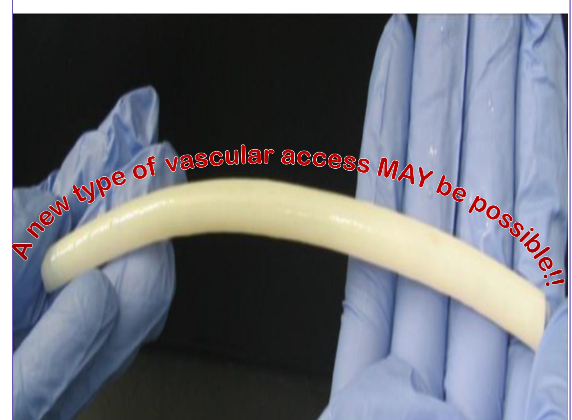
Project Scientist

Phone # 714-456-2334

The HAV-ACCESS Study

Clinical Trial

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

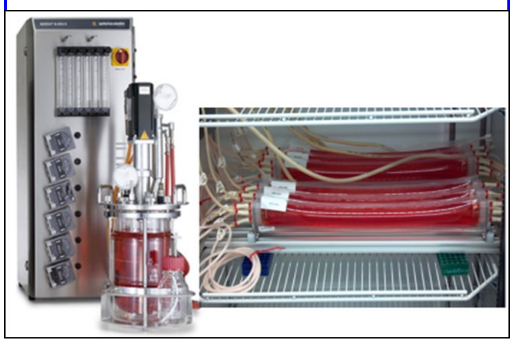


The HAV-ACCESS Study

The purpose of this Phase 3 clinical trial is to compare a widely used autologous arteriovenous fistula (AVF) with a new experimental graft developed by Humacyte called the Human Acellular Vessel or HAV.

What is the HAV?

- A type of graft that is grown in a laboratory from aortic vascular smooth muscle cells (special cells that partially make up normal blood vessels) obtained from an organ donor. The donors have been fully tested to ensure that the donors do not have any infections that could affect you.
- Made of proteins such as collagen (connective tissue) which is a normal part of human blood vessels. The HAV is grown in a special enclosed bag under conditions that mimic a heart pumping. Once the HAV is fully formed, the cells are removed with a series of washes so the HAV does not contain any living cells.



Can I take part in the trial?

You may be eligible to take part in trial the if you:

- Are at least 18 years of age
- Have ESRD (end stage renal disease)
- Are receiving hemodialysis via dialysis catheter and are suitable for the creation of an AVF or implantation of autologous arteriovenous graft (AVG) for hemodialysis access.
- Plan to undergo hemodialysis at a dialysis unit of a participating dialysis provider for at least the first 6 months after study access creation
- Suitable anatomy for implantation of straight or looped graft in either the forearm or upper arm

If you want to be a part of the study and qualify, the HAV or AVF graft will be surgically implanted in your arm just under the skin and attached to your artery and vein. Once your arm heals from this surgery, needles used for dialysis access can be used in the standard fashion.

How does the HAV work?

The HAV will be surgically placed in your arm just like a dialysis graft. Early studies suggest that your own cells may move into the walls of the HAV so that it becomes more like a natural blood vessel. If that happens the HAV may more closely act like a human blood vessel and possibly reduce complications such as clots and infections which, in turn, may mean the HAV could continue to work for a longer period of time compared with a standard AVF.

What will my arm look like if I get an HAV?

- The HAV will look similar to a standard AVF after surgery.