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Humacyte HAV-007 End Stage Renal Disease (ESRD) Clinical Trial

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic at UC Irvine, and the Department of Vascular and Endovascular Surgery

Study Title: A Phase 3 Study to Compare the Efficacy and Safety of Humacyte's Human Acellular Vessel with that of an Autologous Arteriovenous Fistula in Subjects with End-Stage Renal Disease

Lead Investigator: Roy Fujitani, MD

What is the study?

The purpose of this study is to compare a widely used autologous arteriovenous fistula or AVF (a direct surgical connection between your artery and vein) with a new experimental graft (a short piece of tubing) developed by Humacyte called the Human Acellular Vessel or HAV.
You will be randomized into one of two groups: HAV or AVF. You will have an equal chance (50:50) of receiving the HAV or AVF.

How long will my participation last?

The total length of the study may be up to 5 years.

How can I take part in this trial?

At UC Irvine, we will enroll approximately 90 subjects.

Please note this may not be a complete list of eligibility criteria.

Main Inclusion Criteria

- At least 18 years of age.
- ESRD (end stage renal disease).
- Receiving hemodialysis via dialysis catheter and are suitable for the creation of an AVF or implantation of autologous arteriovenous graft (AVG) for hemodialysis access.

Main Exclusion Criteria

- Previous failed AVF or AVG.
- Plan to become pregnant during the study.

How does it work?

The HAV is grown from aortic vascular smooth muscle cells (cells that partially make up normal blood vessels) obtained from an organ donor. The donors have been fully tested to ensure that they do not have any infections that could affect you. As the cells grow, they produce proteins, such as collagen, which is a normal component of human blood vessels. When the HAV is fully formed, the cells are removed so the HAV itself does not contain any living cells.
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. After surgery to implant the HAV, typically the HAV is ready to be used for dialysis in about 4 weeks.

Where is the study conducted?

At the University of California, Irvine Medical Center located in Orange, CA.

Will I be compensated?

You will be reimbursed up to $50.00 at each follow-up visit for any out of pocket expenses, such as parking or transportation fees.

For more information please contact:

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