CLN-PRO-V007 Website Content

Website URL: http://www.humacyte.com/HAV-ACCESS/

HAV-ACCESS

Human Acellular Vessel – A Controlled Comparison of Efficacy and Safety Study

Human Acellular Vessel vs. Arteriovenous Fistula for Hemodialysis Access

Patients **Physicians**

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

PATIENTS

Humacyte HAV-ACCESS Phase III Clinical Trial

Study Population: Patients with kidney failure who are currently receiving hemodialysis with a catheter (e.g. Permcath™) and require placement of a dialysis graft or creation of a dialysis fistula for more permanent dialysis access.

Study Sites: Approximately 20 Sites in the United States

Enrollment: Approximately 240 patients; Randomization: 1:1 AVF:HAV

Study Start Date: August 2017

Follow up period: Up to 5 years

- Sponsor: Humacyte, Inc.
- Contact: Local Study coordinator

Thank you for being a part of the HAV-ACCESS clinical trial. This Phase III study will compare hemodialysis access with the Human Acellular Vessel (HAV) to that with an arteriovenous fistula (AVF), current standard of care for patients needing hemodialysis access. Thank you for your willingness to participate in important clinical research. Click below if you would like to learn more about the HAV-ACCESS clinical trial, the Humacyte vessel and our technology.

Website URL: http://www.humacyte.com/HAV-ACCESS/physicians/

PHYSICANS

ATTENTION PHYSICIAN: The purpose of this website is to alert you that this patient is enrolled in the HAV-ACCESS Phase III AV Access Clinical Trial.

PRIOR TO INTERVENTION: We request that you read Intervention Guidelines and refer to the appropriate Medical Monitor phone number listed below if you have questions regarding interventions to this arteriovenous (AV) access.

This patient's vascular access may be either an autologous arteriovenous fistula (AVF), or the Human Acellular Vessel (HAV).

Be advised, balloon for angioplasty or thrombectomy SHOULD NOT EXCEED 6mm in diameter within the HAV as disruption or tearing of HAV may occur.

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- Contact: Medical Monitor: 1-800-723-2890

The HAV-ACCESS Phase III clinical trial will compare the HAV with a current standard of care AVF when used for hemodialysis access in the above study population. Click above to review Intervention Guidelines, or click below to review cannulation guidelines or if you would like to learn more about the Humacyte technology, the HAV-ACCESS clinical trial, or Phase II clinical trial results

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Website URL: http://www.humacyte.com/HAV-ACCESSs/patients/clinical-trial-synopsis/

Clinical Trial Synopsis

Humacyte's Study: A Controlled Comparison of Efficacy and Safety Study (HAV-ACCESS) between Humacyte's Human Acellular Vessel (HAV) and a current clinical standard, arteriovenous fistula (AVF), for hemodialysis access began enrollment in August of 2017.

Patients with end-stage renal disease (kidney failure) who are currently receiving hemodialysis with a catheter (e.g. Permcath™) and who are suitable candidates for placement of a dialysis graft or creation of a dialysis fistula will be considered for participation in this prospective, multicenter, randomized, comparative study. Patients will be implanted in the forearm or upper arm with either a HAV or AVF. The 1:1 randomization (a 50/50 chance of receiving the HAV or AVF) will occur in the operating room, prior to surgery. All patients will be required to take daily aspirin unless they are already taking another antiplatelet agent e.g., Plavix® (clopidogrel)

Each patient will be followed by study specific visits through 2 years (24 months) of follow up after implantation (whether the study access is open and functioning or not). After 2 years, all subjects with HAV, but only those subjects with a functioning AVF will be followed for up to 5 years (60 months) post-implantation at routine study visits.

Schedule of Study Specific Visits

- Screening Visit (up to 45 days prior to surgery date)
- Day 0 (Surgery day)
- Post op Day 7-15
- 1 month
- 2 months
- 3 months
- 6 months
- 9 months
- 1 year
- 18 months
- 2 years
- Visits will continue every 6 months from month 30 – 60 as long as the access remains open and functional

All visits include:

- A general physical exam
- Evaluation of the study access site
- Documentation of:
- Problems
- Work done to the study access
- Perm cath placement
- Medications

Some visits will include:

- Ultrasound imaging of the study access

- Lab work

Website URL: http://www.humacyte.com/hav-access/patients/humacyte-vessel/

The HUMACYTE HAV is a tissue-engineered blood vessel that is being investigated as a surgical option for vascular access. The HAV is a sterile, vascular tube, composed of human connective tissue and proteins. This complex connective tissue has similarities to human vascular tissue but HAV is non-living. To date, the HAV has been implanted in over 250 patients worldwide in various clinical trials.

To read more about the Humacyte HAV, click here.
