

Now Accepting Patients: Prospective Evaluation of Elastic Restraint to LESSen the Effects of Heart Failure (PEERLESS-HF)

Hypothesis:

Subjects in the HeartNet and optimal medical/device therapy arm will show an improvement in peak VO_2 , 6 minute walk distance and quality of life compared to subjects in the optimal medical/device therapy alone arm

Study Design:

Randomized (1:1), prospective, two-arm comparison, multi-center in the US and Canada (see Figure 1)

Study Management:

Sponsor

Paracor Medical, Inc., Sunnyvale, CA

Principal Investigator

William Abraham, MD, FACP, FACC (Ohio State University)

Core Laboratories

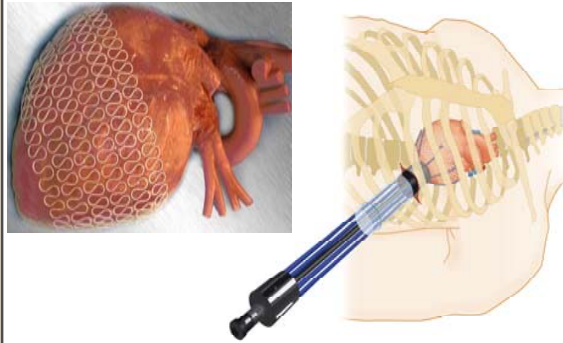
- Cardiopulmonary Exercise Core Laboratory (Henry Ford Hospital)
- Echocardiographic Core Laboratory (Hospital of the Univ. of Pennsylvania)

Independent Data Review

- Data Safety Monitoring Committee
- Clinical Events Committee

Investigational Device:

HeartNet Ventricular Support System



- Novel device, delivered with special delivery system through mini-thoracotomy
- Super-elastic compliant nitinol structure
- Pre-sized based on echo measurements
- Self-anchoring, self-tensioning
- Overall procedure time is generally completed in about 1 hour
- Defibrillation & pacing compatible
- MRI compatible

Inclusion Criteria:

General

- Symptomatic heart failure (ACC/AHA Stage C)
- Stable medical/device therapy for 3 m
- $\text{EF} \leq 35\%$
- CRT or CRT-D OK, if placed ≥ 3 m before enrollment or do not anticipate < 6 m after

Specific

- 6 MWD 150 – 450 m
- pVO_2 for males, 10 – 20; females, 9 – 18; or $\text{pVO}_2 < 24$, if percent predicted $\text{pVO}_2 < 70\%$
- LVEDD < 85 mm and index < 40 mm/m^2
- HF duration ≥ 6 m

Key Exclusion Criteria:

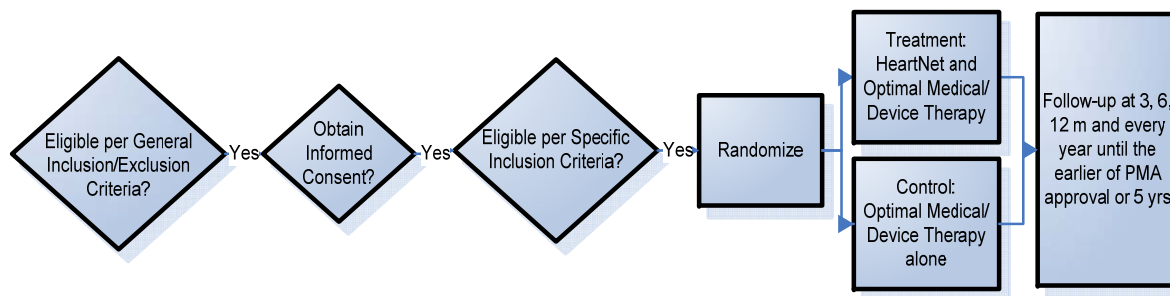
Patient History

- ≥ 75 yrs
- MI, stroke, TIA, surgery, ICD within 3 m
- Uncontrolled medical condition with incr. surgical risk
- Hemoglobin $< 10\text{gm/dL}$ or creatinine > 2.5 mg/dL

Surgical / Anatomical

- Anatomical mitral valve regurg of 2+ or greater
- Pulmonary fxn tests: $\text{FEV}_1 < 1$ L, or if FEV_1 between 1 and 3L $\text{FEV}_1/\text{FVC} < 60\%$
- Cardiac or thoracic condition that might require correction

Figure 1. PEERLESS-HF Trial Flow.



List of Investigational Sites:

US Allegheny General Hospital Pittsburgh, PA; BryanLGH Heart Institute Lincoln, NE; Caritas St. Elizabeth's Medical Center Boston, MA; Christiana Care Health System Newark, DE; Emory University Hospital Atlanta, GA; Genesis Medical Center Davenport, IA; Inova Heart & Vascular Institute/Fairfax Hospital Falls Church, VA; Intermountain Medical Center Salt Lake City, UT; Mid America Heart Institute Kansas City, MO; Midwest Heart Foundation Lombard, IL; Minneapolis VA Medical Center Minneapolis, MN; Montefiore Medical Center Bronx, NY; Morristown Memorial Hospital Morristown, NJ; Oklahoma Heart Hospital Oklahoma City, OK; Penn State Milton S. Hershey Medical Center Hershey, PA; St. Paul Heart Clinic St. Paul, MN; St. Thomas Hospital Nashville, TN; St. Vincent Hospital and Health Services Indianapolis, IN; Lindner Clinical Trial Center Cincinnati, OH; Ohio State University Medical Center Columbus, OH; Stern Cardiovascular Center Germantown, TN; University of Alabama at Birmingham Birmingham, AL; UCSF Medical Center San Francisco, CA; University of Colorado Health Sciences Center Aurora, CO; University of Florida, Shands Gainesville, FL; University of Maryland Medical Center Baltimore, MD; University of Rochester Medical Center Rochester, NY; USC Keck School of Medicine Los Angeles, CA; Wayne State University/Oakwood Hospital Detroit, MI.

Canada Foothills Medical Centre Calgary, Alberta; London Health Sciences Centre London, Ontario; McGill University Health Centre Montreal, Quebec; St. Boniface General Hospital, Winnipeg, Manitoba; St. Paul's Hospital, Vancouver, British Columbia; Toronto General Hospital Toronto, Ontario

For Further Information:

To refer patients, please contact Linda Clark at lclark@paracor.com

Additional information is available at www.peerless-hf.com and www.clinicaltrials.gov (NCT00382863)

Caution: Investigational device. Limited by Federal (or United States law) to investigational use. Investigational Device. To be used by Qualified Investigators only.

