The PEECH™ Trial

Prospective Evaluation of EECP in Congestive Heart Failure

THE PEECH STEERING COMMITTEE

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Vasomedical Inc. EECP®

2080 Rev.0

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ENROLLING STUDY CANDIDATES

The PEECH Trial is a large-scale efficacy study of Enhanced External Counterpulsation in the treatment of congestive heart failure. Study enrollment seeks patients with mild to moderate heart failure NYHA class 2 or 3 with LVEF of 35% or less who have heart failure of either ischemic or idiopathic etiology. Patients are randomized in a 50/50 split to either optimal medical therapy (per HFSA guidelines) or the same plus a course of 35 one-hour EECP treatments. Patients are followed for six months post-treatment and evaluated by VO_2 max stress testing, functional class, neurohumoral factors, and quality of life outcomes. Patient target enrollment is 180.

Trial includes free testing and medical examinations for study participants.

Study centers are located in the following cities:

Arkansas
Little Rock

Arizona
Gilbert/Phoenix

California
La Jolla
Los Angeles
San Diego

Colorado
Denver

Florida
Atlantis/WPB
Miami Beach
Mt.Dora/Orlando

Illinois
Chicago

Massachusetts
Falmouth

Minnesota
Minneapolis
Rochester
St. Paul

New York
Bronxville
Staten Island
Stony Brook
Syracuse

North Carolina
Chapel Hill

Ohio
Cincinnati
Cleveland
Columbus

Pennsylvania
Philadelphia
Pittsburgh

Tennessee
Memphis

Texas
San Antonio

Virginia
Newport News

England
Hull

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Applications and Recruitment Assistance
Vasomedical, Inc. 180 Linden Avenue, Westbury, NY 11590

Heart failure treatment must be optimized in ALL patients prior to enrollment.

A prospective, randomized, single-blind study of EECP® vs. Usual Care in chronic, stable heart failure patients.

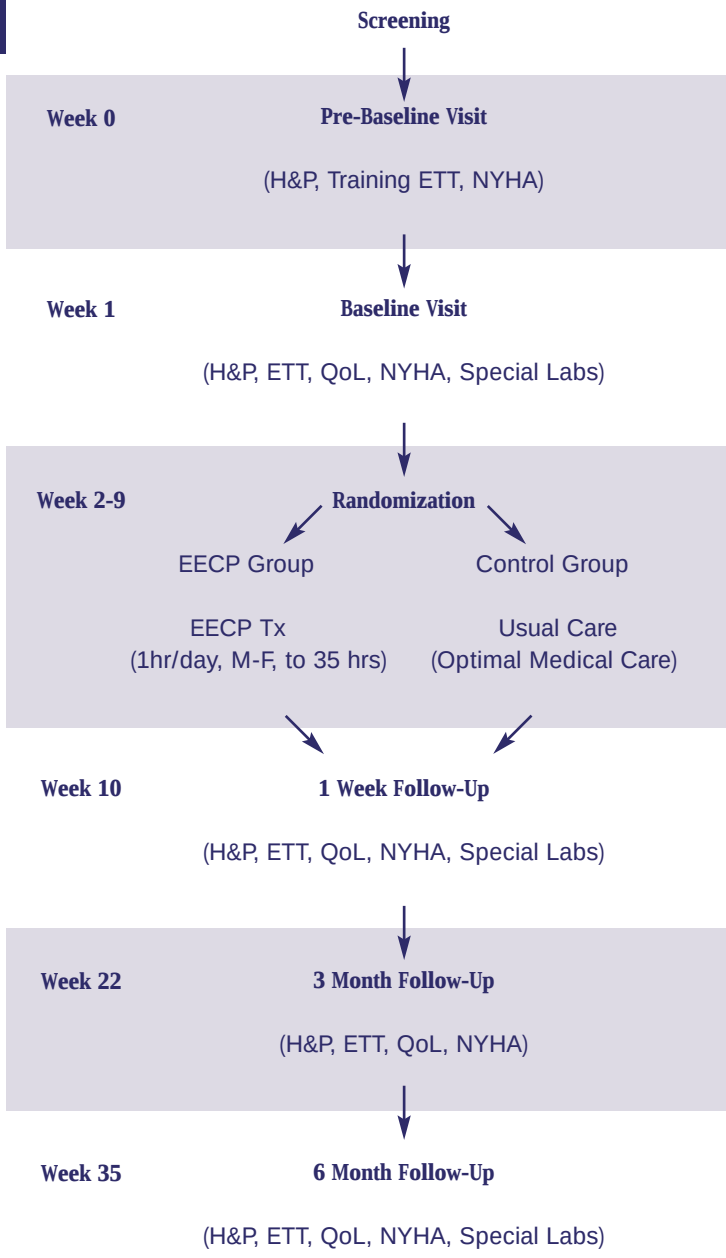
Study Inclusions

1. NYHA Class II or III heart failure with EF ≤ 35% (within last 3 months); ischemic or idiopathic etiology.
2. Ability to exercise on a treadmill ≥ 3 minutes (must be limited by symptoms of heart failure, NOT by claudication, angina, ischemic ECG changes, or non-cardiac disease, e.g. pulmonary disease).
3. Stable condition (no medication changes in the last 2 weeks prior to 1st study treatment visit).
4. Less than 1+ edema, i.e. no pretibial edema and no more than trace ankle edema.
5. If treated with digoxin, digoxin blood levels of ≤ 1.75 nanogram/ml.
6. Serum creatinine levels of ≤ 2.5 mg/dl.
7. Receiving treatment with an ACE-inhibitor for at least 1 month prior to the first study visit or ACE-inhibitor is not tolerated.
8. Receiving treatment with a beta-blocker for at least 3 months prior to 1st study visit or there is a documented reason for not having used a beta-blocker.

Study Exclusions

1. Prior treatment with EECP.
2. Acute coronary syndrome within past 6 weeks.
3. Non-bypassed left main coronary artery with a luminal stenosis ≥ 50%, except when bypass is not feasible or is refused.
4. CABG within past 3 months or PCI within past 6 months.
5. Cardiac catheterization within past 2 weeks.
6. Arrhythmia that would significantly interfere with EECP device.
7. COPD with FEV1 of ≤ 1.5 L.
8. Clinically significant valvular heart disease.
9. Acute myocarditis.
10. ICD if triggered within past 3 months.
11. History of deep vein thrombosis, phlebitis, stasis ulcer and/or pulmonary embolism.
12. History of aortic aneurysm.
13. Coagulation abnormalities with INR > 2.5. (Coumadin may be adjusted.)
14. Uncontrolled hypertension (SBP ≥ 180 mmHg and/or DBP ≥ 110 mmHg).
15. Inability to give Informed Consent and/or incapacity to comply with all study requirements.

PROTOCOL SCHEDULE



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