CardiAMP™ Cell Therapy Heart Failure Trial

STUDY DESCRIPTION

Brief Summary
This is a prospective, multi-center, randomized (3 Treatment : 2 Sham Control), sham-controlled, patient- and evaluator-blinded study comparing treatment with the CardiAMP cell therapy to a sham treatment. A roll-in phase with a maximum of 10 subjects may occur.

Condition or Disease: Heart Failure

Intervention/treatment: Biological: Autologous cell therapy
Other: Sham

Phase: Phase 3

DETAILED DESCRIPTION

Heart failure is a clinical condition in which the output of blood from the heart is insufficient to meet the metabolic demands of the body. In 2015, the American Heart Association, or AHA, report on heart disease statistics estimated that there are 5.7 million Americans over the age of 20 that have heart failure. Heart failure is increasingly prevalent due to the aging population and the increase in major cardiovascular risk factors, including obesity and diabetes. The AHA also estimates that one in five adults will develop heart failure after the age of 40. During heart failure progression, the heart steadily loses its ability to respond to increased metabolic demand, and mild exercise soon exceeds the heart's ability to maintain adequate output. Towards the end stage of the disease, the heart cannot pump enough blood to meet the body's needs at rest. At this stage, fluids accumulate in the extremities or in the lungs making the patient bedridden and unable to perform the activities of daily living. The long-term prognosis associated with heart failure is approximately 50% mortality at five years following the initial diagnosis.

CardiAMP is a comprehensive therapeutic treatment that comprises (i) a point of care cell processing platform, and (ii) a biotherapeutic delivery system. CardiAMP is the first comprehensive therapeutic treatment utilizing a patient's own cells for the treatment of ischemic systolic heart failure, which is heart failure that develops after a heart attack. In the screening process, the physician extracts a small sample of the patient's bone marrow in an outpatient procedure performed under local anesthesia. The clinic sends the sample to a centralized diagnostic lab, which tests the sample. During the treatment, a clinician harvests and then prepares the patient's own bone marrow mononuclear cells, or autologous cells, using the CardiAMP point of care cell processing platform, which a cardiologist then delivers into the heart using the Helix biotherapeutic delivery system.

BioCardia intends to submit data obtained from this clinical trial in a Pre-Market Approval Application to the United States Food and Drug Administration

STUDY DESIGN

Study Type: Interventional
Estimated Enrollment: 250 participants
Intervention Model: Parallel Assignment
Masking: Double (Participant, Outcomes Assessor)
Primary Purpose: Treatment
Official Title: CardiAMP™ Cell Therapy Heart Failure Trial

Study Start Date: December 2016
Estimated Primary Completion Date: December 2022
Estimated Study Completion Date: December 2024

ARMS AND INTERVENTIONS

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<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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<tr>
<td>Experimental: CardiAMP cell therapy Placement of an introducer guidewire, performance of a left ventriculogram, and treatment with autologous cell therapy.</td>
<td>Biological: Autologous cell therapy Autologous cell therapy delivered into the heart muscle using the CardiAMP Cell Therapy System. The CardiAMP Cell Therapy System consists of the CardiAMP Cell Separator, a cardiac delivery catheter, and flexible tip guide catheter.</td>
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<tr>
<td>Sham Comparator: Sham Comparator Placement of an introducer guidewire and performance of a left ventriculogram with no autologous cell therapy treatment.</td>
<td>Other: Sham An introducer guidewire is placed into the heart and left ventriculography is performed just like it is in the Experimental Arm but no autologous cell therapy is delivered.</td>
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OUTCOME MEASURES

Primary Outcome Measures: 1. A composite endpoint based on a 3-tiered Finkelstein-Schoenfeld (FS) hierarchical analysis. [ Time Frame: 12 Months ]
2. The tiers include (1) all-cause death, (2) non-fatal MACCE events, and (3) change for 6MWd from baseline to month 12.
3. Survival Rate [ Time Frame: 12 Months ]
4. Survival rate compared between both study arms (non-inferiority, treatment vs sham)
5. Major Adverse Cardiac Events (MACE) [ Time Frame: 12 months ]
6. Freedom from MACE, defined as the composite of all-cause death, hospitalization for worsening heart failure, nonfatal recurrent myocardial infarction, placement of a left ventricular assist device (LVAD), or heart transplantation (non-inferiority, treatment vs sham)
7. Minnesota Living with Heart Failure Questionnaire (MLHFAQ [ Time Frame: 12 months ]
Mean change in quality of life score as measured by the MLHFAQ at 12 months compared to baseline (superiority, treatment vs sham)
4. Time to first MACE [ Time Frame: 12 months ]
Time (in days) to first MACE during the 12 months after the baseline measurements (superiority, treatment vs sham)
5. Survival rate [ Time Frame: 12 months ]
Survival rate compared between both study arms (superiority, treatment vs sham)

ELIGIBILITY CRITERIA

Ages Eligible for Study: 21 to 90 Years (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
New York Heart Association (NYHA) Class II or III A diagnosis of chronic ischemic left ventricular dysfunction secondary to myocardial infarction (MI). On stable evidence-based medical and device therapy for heart failure or post-infarction left ventricular dysfunction, per the 2013 ACC/AHA Heart Failure guidelines, for at least three (3) months prior to randomization. Left ventricular ejection fraction between 20% and 40%. Qualification of a pre-procedure screening of bone-marrow aspiration

Exclusion Criteria:
• Other cardiac or vascular system or other health-related criteria which may be seen in a patient's history and physical examination.

CONTACTS AND LOCATIONS

Contacts
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Locations

United States, Alabama Cardiology PC Birmingham
United States, Arizona Mayo Clinic Phoenix
United States, California USC Los Angeles
United States, California Cedars Sinai Medical Center Los Angeles
United States, California Stanford Medical Center, Stanford Health Care Palo Alto
United States, California California Pacific Medical Center San Francisco
United States, Colorado University of Colorado, Denver Aurora
United States, District of Columbia MedStar Health Research Institute Washington
United States, Florida Morton Plant Mease Health Care Clearwater
United States, Florida University of Florida - College of Medicine/ div of Cardiovascular Medicine Gainesville
United States, Illinois Northwestern University Chicago
United States, Iowa Iowa Heart Des Moines
United States, Maryland John Hopkins University School of Medicine - Dept of Cardiology Baltimore
United States, Maryland Suburban Hospital Bethesda
United States, Michigan Henry Ford Hospital Detroit
United States, Michigan Michigan Cardiovascular Institute Saginaw
United States, Michigan Michigan Heart - St.Joseph Mercy Health System (Trinity Health) Ypsilanti
United States, Minnesota University of Minnesota Minneapolis
United States, New Jersey Atlantic Health System Morristown
United States, New York New York University School of Medicine New York
United States, New York Cornell University New York
United States, Oklahoma Oklahoma Heart Tulsa
United States, Texas Texas Heart Institute Houston
United States, Virginia Virginia Commonwealth University (VCU) Medical Center Richmond
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Sponsors and Collaborators
BioCardia, Inc.

Investigator
Principal Investigator: Carl Pepine, MD University of Florida
Principal Investigator: Amish Raval, MD University of Wisconsin, Madison

MORE INFORMATION
Other Publications

Responsible Party: BioCardia, Inc.
ClinicalTrials.gov Identifier: NCT02438306
Other Study ID Numbers: BC-14-001
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Last Update Posted: December 15, 2021
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Individual Participant Data (IPD) Sharing Statement: Plan to Share IPD: No

Additional relevant MeSH terms: Heart Failure Cardiovascular Diseases Heart Diseases