ALLSTAR

NCT01458405

Principal Investigator: Dr. Safwan Kassas (Covenant)

Condition: Myocardial Infarction

Biological: CAP-1002 Allogeneic Cardiosphere- Derived Cells

Official Title: Randomized, Double-Blind, Placebo-Controlled Phase I/II Study of the Safety and Efficacy of Intracoronary Delivery of Allogeneic Cardiosphere-Derived Cells in Patients With an Anterior Myocardial Infarction and Ischemic Left Ventricular Dysfunction

Sponsor: Capricor Inc.

Purpose: The purpose of this study is to determine whether Allogeneic Cardiosphere-Derived Cells (CAP-1002) is safe and effective in decreasing infarct size in patients with a myocardial infarction.

Inclusion Criteria

1. History of anterior MI within the prior 4 weeks to 12 months due to coronary artery atherosclerotic disease and evidenced by typical ischemic symptoms, serial ST-T changes (new ST elevation or new left bundle block) and elevated troponin or CK-MB >5 times the upper limit of normal with at least one of the following, based on standardly accepted definition of acute MI: development of pathological Q wave ECG changes, imaging evidence of new loss of viable myocardium, or new regional wall motion abnormalities.
2. History of percutaneous coronary intervention (PCI), with stent placement resulting in TIMI flow = 3, in the left anterior descending coronary artery supplying the infarcted, dysfunctional territory and through which the treatment will be infused.
3. At least one historical assessment of left ventricular ejection function (LVEF) ≤0.45 as determined by any one of the standard modalities (echocardiography, ventriculogram, nuclear imaging, CT and/or MRI). For subjects that fulfill the criteria of Recent MI (i.e., within 90 days of MI) at time of screening visit: assessment must be post-reperfusion after index MI and be the most recent test prior to signing informed consent. For subjects that fulfill the criteria of Chronic MI (i.e., greater than 90 days from MI) at time of screening visit: assessment must be at least 21 days post-reperfusion after index MI and the most recent test prior to signing informed consent. Note: subjects may screen as a Recent MI but be randomized into the Chronic MI strata if the infusion date is > 90 days post-MI.
4. Left ventricular infarct size of ≥ 15% of left ventricular mass as determined by screening MRI, with associated thinning and/or hypokinesis, akinesis, or dyskinesis, with no large aneurysmal area in the anterior/anterolateral/anteroseptal regions . In subjects with infarcts in >1 myocardial wall, >50% of the total LV scar should be in the anterior/anterolateral/anteroseptal regions.
5. No further revascularization clinically indicated at the time the subject is assessed for participation in the clinical trial.
6. Ability to provide informed consent and follow-up with protocol procedures.
7. Age ≥18 years.

Exclusion Criteria

1. Subjects with a history of coronary artery bypass surgery, and a graft (left internal mammary artery or saphenous vein graft) attached to the left anterior descending coronary artery.
2. Diagnosed or suspected myocarditis.
3. History of cardiac tumor, or cardiac tumor demonstrated on screening MRI.
4. History of acute coronary syndrome in the 4 weeks prior to study infusion.
5. History of previous stem cell therapy.
6. History of radiation treatment to the central or left side of thorax.

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Exclusion Criteria Continued:

7. Current or history (within the previous 5 years) of systematic auto-immune or connective tissue disease including, but not limited to, giant cell myocarditis, cardiac or systemic sarcoidosis, Dressler's syndrome, chronic, recurrent or persistent pericarditis.
8. History of or current treatment with immunosuppressive, anti-inflammatory, or other agents to treat manifestations of systemic immunologic reactions, including chronic systemic corticosteroids, biologic agents targeting the immune system, anti-tumor and anti-neoplastic drugs, anti-VEGF, or chemotherapeutic agents within 3 months prior to enrollment.
9. Prior of planned ICD and/or pacemaker placement.
10. Estimated glomerular filtration rate < 30 mL/min.
11. Participation in an ongoing protocol studying an experimental drug or device, or participation in an interventional clinical trial within the last 30 days.
12. Diagnosis of arrhythmogenic right ventricular cardiomyopathy.
13. Current alcohol or drug abuse or an inability to comply with protocol-related procedures.
14. Pregnant/nursing women and women of child-bearing potential without use of active and highly reliable contraception.
15. Human Immunodeficiency Virus (HIV) infection.
16. Viral hepatitis.
17. Uncontrolled diabetes (HbA1c>9%)
18. Abnormal liver function (SGPT > 3 times the upper reference range) and/or abnormal hematology (hematocrit < 25%, WBC < 3000 µl, platelets < 100,000 µl) studies without a reversible, identifiable cause.
19. Sustained ventricular tachycardia (VT) or non-sustained ventricular tachycardia > 30 beats, not associated with the acute phase of a previous MI (> 48 hours after the MI onset) or a new acute ischemic episode.
20. Ventricular fibrillation not associated with a new acute ischemic episode.
21. New York Heart Association (NYHA) Class IV congestive heart failure.
22. Evidence of tumor on screening chest/abdominal/pelvic (body) CT scan.
23. Any prior transplant.
24. Known hypersensitivity to dimethyl sulfoxide (DMSO)
25. Known hypersensitivity to bovine products.
26. Any malignancy within 5 years (except for in-situ non-melanoma skin cancer and in-situ cervical cancer) of signing the ICF.
27. Any condition or other reason that, in the opinion of the Investigator or Medical Monitor, would render the subject unsuitable for the study.

Source: https://clinicaltrials.gov/ct2/show/NCT01458405

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