Administration of Allogeneic-MSC in Patients With Non-Ischemic Dilated Cardiomyopathy

NCT04476901

Status	RECRUITING
Phase	Phase 2
Sponsor	Joshua M Hare
Enrollment	136 participants

Key Eligibility Criteria

Inclusion (6)

- In order to be eligible to participate in this study, an individual must meet all of the following criteria:
- Men and women aged 18 to 80 years (inclusive) at the time of signing the informed consent form.
- Diagnosis of NIDCM with left ventricular ejection fraction d45%.
- Appropriate guideline-directed optimal medical therapy for non-ischemic cardiomyopathy. At a minimum, subjects must be on beta blockers and angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) or Angiotensin Receptor Neprilysin Inhibitors (ARNI) or have appropriate medical indication precluding use of one or both of these agents. Subjects must be on a stable regimen for at least 30 days prior to the procedure. Dose titration is allowed.
- Be a candidate for cardiac catheterization*

... and 1 more (see full listing online)

Exclusion (40)

- An individual who meets any of the following criteria will be excluded from participation in this study:
- Be eligible for or require standard-of-care surgical or percutaneous intervention for the treatment of non-ischemic dilated cardiomyopathy
- Clinical manifestation of coronary artery disease (CAD) (e.g., chest pain and concomitant clinical findings such as electrocardiogram changes suggestive of coronary ischemia, myocardial infarction) or evidence of endocardial or transmural scar on cardiac MRI suggestive of undiagnosed CAD or history of percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG). Be indicated for or require coronary artery revascularization
- Documented presence of epicardial stenosis of 70% or greater in one or more major epicardial coronary arteries
- Valvular heart disease including 1) aortic valve prosthesis, mechanical mitral valve, and mitral valve clip; 2) severe aortic valve insufficiency/regurgitation within 12 months of consent*

... and 35 more (see full listing online)

Locations (4 total)

Stanford University, Stanford, California, United States
University of Miami Miller School of Medicine, Miami, Florida, United States
University of Louisville, Louisville, Kentucky, United States
... and 1 more locations