

Clinical trial to use heart-derived stem cells to restore heart tissue, function

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A multi-center team of researchers are planning a clinical trial using cardiosphere-derived cells (CDCs) (a heterogeneous cluster of proliferating cardiac cells that include mesenchymal stem cells) to regenerate the tissue and improve function of the heart in patients who have suffered heart attacks (myocardial infarction, MI).

The study will use allogeneic CDCs - cells derived from donors other than the patients. In previous pre-clinical and clinical studies, CDCs have been shown to have low immunogenicity and unlikely to result in immune rejection of the cells.

The study, a randomized, double-blind, placebo-controlled phase 1 and 2 study to determine safety, will be carried out by researchers at Cedars-Sinai Heart Institute, Minneapolis Heart Institute, Scripps Medical Center, University of California at San Diego, Duke Clinical Research Institute, Johns Hopkins Hospital, and Columbus Biometrics. The study design and rationale will be published in a future issue of *Cell Transplantation*.

The team's previous studies have revealed that CDC transplantation was safe and helped improve ventricular function and reduce scar tissue.

"CDC transplantation has been shown to improve the outcome in infarcted myocardium and has an excellent safety profile," said Dr. Timothy D. Henry, Director of the Division of Cardiology, Cedars-Sinai Heart Institute. "While autologous transplantation has been shown to

curtail immune responses, obtaining CDCs from the patients is not feasible as it is cost-prohibitive and is associated with many logistical complications. Use of other-donated allogeneic cells, however, allows for more efficient processing and transplantation and previous studies have shown significant improvement and tolerability in subjects without the need for immunosuppression."

Named the "ALLogeneic Heart STem Cells to Achieve Myocardial Regeneration" (ALLSTAR) trial, the study is the first randomized, double-blind, placebo-controlled trial to determine the safety and efficacy of allogeneic CDCs for patients with MI.

The study will examine several clinical endpoints that indicate cardiac regeneration, including cardiac and clinical function, quality of life, symptom alleviation, and safety.

Based on the results of the ALLSTAR Phase 1 trial, researchers predict that infusing CDCs will result in improvement for patients with MI.

"Cultural and lifestyle factors, as well as the increasing age of the population, have culminated to make heart health a significant area of interest in medicine," said Dr. Shinn-Zong (John) Lin, Tzu Chi Hospital, Hualien City, Taiwan, and Co-Editor-in-Chief of Cell Transplantation. "Cell therapy may play an integral role in the way that heart diseases are treated. This clinical study may hold promise for future approaches for treating MI."

More information: , ALLogeneic Heart STem Cells to Achieve Myocardial Regeneration (ALLSTAR) trial: Rationale & Design, *Cell Transplantation* (2016). [DOI: 10.3727/096368916X692933](https://doi.org/10.3727/096368916X692933)

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