

Research shows stem cell infusion could be effective for most common type of heart failure

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Cardiac stem cells could be an effective treatment for a common but difficult-to-treat type of heart failure, a new study from the Cedars-Sinai Heart Institute shows.

The study, published today, has led to clearance by the U.S. Food and Drug Administration (FDA) for an Investigational New Drug (IND) application to test the cells in patients.

Appearing in the *Journal of the American College of Cardiology Basic and Translational Science*, the study shows that weeks after infusions of cardiosphere-derived cells (CDCs), the heart-pumping function returned to normal in [laboratory rats](#) with hypertension and diastolic [heart failure](#).

Formerly known as diastolic heart failure, the diagnosis now called heart failure with preserved [ejection fraction](#) is a condition in which the heart muscle becomes so stiff that its pumping chambers cannot properly fill with blood. Even though the heart's ability to pump blood to the body remains normal, its inability to fill with blood over time can lead to fluid buildup. This affects other body organs and causes fluid congestion, especially in the lungs. The hard-to-treat condition leads to extreme fatigue and difficulty breathing.

Today, more than half of patients with heart failure have heart failure with preserved ejection fraction, which is particularly common in women and in patients who also have diabetes, obesity and hypertension.

"There is an enormous unmet clinical need, but nobody has a clue as to how to treat it," said Eduardo Marbán, MD, PhD, director of the Cedars-Sinai Heart Institute, noting that approximately 3 million people in the U.S. have this form of heart failure. "None of the drugs that work in regular

heart failure work for these patients."

Marbán, an international leader in cardiac stem cell research, led the Cedars-Sinai team that completed the world's first cardiac stem cell infusion in 2009. Results from that clinical trial, published in *The Lancet*, showed that stem cells could regenerate new, healthy [heart muscle](#) after a heart attack. Marbán's work now also examines whether stem cells can be used to heal other heart ailments.

In the new research study, 34 laboratory rats with hypertension and heart failure with preserved ejection fraction were given infusions of cardiac stem cells. A second group of 34 laboratory rats were given a placebo. Four weeks later, the rats in the stem cells group had normalized heart function and their hearts were able to fill normally. Those in the placebo group became progressively sicker and died prematurely.

"When patients with preserved ejection fraction get sick, they might be hospitalized and they might be prescribed medications like diuretics, which reduce the buildup of fluid in the lungs. The patients might get better symptomatically, but we haven't really treated the underlying condition," said Marbán, the lead author of the study. "This research suggests that [cardiac stem cells](#) could be effective as a therapeutic agent, and there is a specific treatment we can try when everything else has failed."

The study was funded by the Cedars-Sinai Board of Governors Heart Stem Cell Center. General support for Marbán's laboratory is provided by the National Institutes of Health.

Meanwhile, on the basis of these findings, Marbán has recently obtained clearance from the FDA for an Investigational New Drug (IND) application to use cardiospheres to treat humans with heart

failure with preserved ejection fraction. The stem cells, manufactured by Capricor Inc. as their product CAP-1002, have been used in other human clinical trials.

The process to grow cardiac-derived [stem cells](#) was developed by Marbán when he was on the faculty of Johns Hopkins University. Capricor has licensed the process from Johns Hopkins for clinical and commercial development. Capricor has licensed additional intellectual property from Cedars-Sinai and the University of Rome. Cedars-Sinai and Marbán have financial interest in Capricor.

Provided by Cedars-Sinai Medical Center

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