

## 幹細胞治療は心不全の転帰を改善する (LBCT 1172-079)

ixCELL-DCM: 試験的幹細胞治療後に心不全患者の転帰が改善した

ixCELL-DCM: Heart failure patients experience improved outcomes following investigational stem cell treatment

患者自身の骨髄から得た幹細胞による試験的幹細胞治療は重症心不全患者の転帰を有意に改善した。とAmerican College of Cardiology年次集会で発表され、同時にLancetに掲載された。この第II相試験において、医師は虚血性拡張型心筋症と診断された患者109人を12か月間追跡した。幹細胞治療を受けた患者58人においては、プラセボを投与された患者51人よりも死亡、入院および症状増悪率が37%低かった。幹細胞治療を受けた患者のうち死亡したのは3.4%であったのに対し、プラセボ投与群では13.7%であった。

### Full Text

An investigational stem cell therapy derived from patients' own blood marrow significantly improved outcomes in patients with severe heart failure, according to a study from the Cedars-Sinai Heart Institute.

The research was presented as a late-breaking clinical trial at the American College of Cardiology Scientific Sessions and simultaneously published in *The Lancet*.

"This is an important step forward for heart patients in particular and for stem cell medicine in general," said Timothy D. Henry, M.D., director of the Cardiology Division at the Cedars-Sinai Heart Institute and one of the study's lead authors. "The results indicate that stem cells could be ushering in a bright new era in heart failure treatments."

Called ixmyelocel-T, the stem cell treatment developed by pharmaceutical company Vericel is made from a patient's own bone marrow. A sample of marrow is extracted from the patient and sent to a laboratory, where it undergoes a two-week process to rapidly multiply the number of stem cells and enhance their quality. The stem cell-rich marrow is then infused into the patient's heart muscle during a minimally invasive, catheter-based procedure.

"Our intent is to increase the number of functioning cells in the heart muscle, which, in turn, strengthen the heart and result in alleviating or slowing the advance of severe heart failure," Henry said.

In the Phase II study, physicians followed 109 patients over a 12-month period. All were diagnosed with ischemic cardiomyopathy, a type of heart failure that usually results from a heart attack or coronary artery disease. The 58 patients who received the stem cell therapy showed a 37 percent lower rate of deaths, hospitalizations and worsening symptoms compared to 51 patients who received a placebo.

Of patients who received stem cells, 3.4 percent died compared to 13.7 percent of placebo patients who died. In addition, 37.9 percent of those who received stem cells were hospitalized with cardiovascular issues during the study vs. 49 percent of patients who received the placebo.

"Our focus is on finding each of our patients the most advanced treatment for their disease," said Eduardo Marbán, M.D., Ph.D., director of the Cedars-Sinai Heart Institute. "Stem cells offer us an opportunity to improve cardiac care, expand treatment options and transform the future of heart medicine."

Henry is a lead author along with Amit N. Patel, M.D., M.S., of the University of Utah. Cedars-Sinai also was one of the lead enrollers in the study.

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