

New human trial shows stem cells are effective for failing hearts

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Patients with severe ischemic heart disease and heart failure can benefit from a new treatment in which stem cells found in bone marrow are injected directly into the heart muscle, according to research presented at the American College of Cardiology's 63rd Annual Scientific Session.

"Our results show that this stem cell treatment is safe and it improves [heart](#) function when compared to placebo," said Anders Bruun Mathiasen, M.D., research fellow in the Cardiac Catheterization Lab at Rigshospitalet University Hospital Copenhagen, and lead investigator of the study. "This represents an exciting development that has the potential to benefit many people who suffer from this common and deadly disease."

Ischemic [heart disease](#), also known as coronary artery disease, is the number one cause of death for both men and women in the United States. It results from a gradual buildup of plaque in the heart's coronary arteries and can lead to chest pain, heart attack and [heart failure](#).

The study is the largest placebo-controlled double-blind randomized trial to treat patients with chronic ischemic heart failure by injecting a type of stem cell known as mesenchymal stromal cells directly into the [heart muscle](#).

Six months after treatment, patients who received stem cell injections had improved heart pump function compared to patients receiving a placebo. Treated patients showed an 8.2-milliliter decrease in the study's

primary endpoint, end systolic volume, which indicates the lowest volume of blood in the heart during the pumping cycle and is a key measure of the heart's ability to pump effectively. The placebo group showed an increase of 6 milliliters in end systolic volume.

The study included 59 patients with chronic [ischemic heart disease](#) and severe heart failure. Each patient first underwent a procedure to extract a small amount of bone marrow. Researchers then isolated from the marrow a small number of mesenchymal stromal cells and induced the cells to self-replicate. Patients then received an injection of either saline placebo or their own cultured mesenchymal stromal cells into the heart muscle through a catheter inserted in the groin.

"Isolating and culturing the stem cells is a relatively straightforward process, and the procedure to inject the [stem cells](#) into the heart requires only local anesthesia, so it appears to be all-in-all a promising treatment for patients who have no other options," Mathiasen said.

Although there are other therapies available for patients with ischemic heart disease, these therapies do not help all patients and many patients continue to face fatigue, shortness of breath and accumulation of fluid in the lungs and legs.

Previous studies have shown mesenchymal stromal cells can stimulate repair and regeneration in a variety of tissues, including heart muscle. Mathiasen said in the case of ischemic heart failure, the treatment likely works by facilitating the growth of new blood vessels and new heart muscle.

The study also supports findings from previous, smaller studies, which showed reduced scar tissue in the hearts of patients who received the stem cell treatment, offering additional confirmation that the treatment stimulates the growth of new [heart muscle cells](#).

The researchers will continue to monitor the patients to assess their long-term outcomes.

"We hope that the improvements in heart pump function will not only improve the patients' symptoms but also will result in increased survival for these severely diseased [patients](#)," Mathiasen said.

A larger, Phase III clinical trial will be needed to move toward approval of this treatment as a more widely used therapy for ischemic heart failure.

"Our results should offer sufficient evidence that a larger trial is indeed warranted as a next step," Mathiasen said.

Provided by American College of Cardiology

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