

First U.S. patient enrolled in stem cell transplantation/cardiac bypass study aimed at improving heart failure

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A 59-year-old Houston man became the first individual in the United States to enroll in a study using stem cell transplantation during cardiac bypass to treat severe heart failure.

Clinician-researchers at the Methodist DeBakey Heart & Vascular Center are investigating whether stem cell infusion, delivered during bypass surgery, will generate new blood vessels and improve heart function more than what is accomplished through bypass surgery alone.

The individual underwent a four-hour procedure Tuesday afternoon but because he is enrolled in a single-blind research study, he will not know if he received his own stem cells until study results are released.

"Unlike previous studies where we injected stem cells only, this study includes [stem cell transplantation](#) during cardiac bypass surgery. The goal is to enhance the bypass surgery by causing the formation of new blood vessels at the site of injection," said Dr. Brian Bruckner, cardiac surgeon and principal investigator on the research study at Methodist.

In this study, individuals randomized to receive stem cells will have their stem cells harvested from their own bone marrow in the operating room while they are under anesthesia. After the bone marrow cells are harvested, Bruckner and Methodist cardiovascular surgeon Dr. Michael Reardon perform the bypass procedure. The cells are simultaneously

processed to separate stem cells from bone marrow. After performing the bypass, the surgeons then inject the stem cells into the subject's heart, and the procedure is complete.

The Methodist DeBakey Heart & Vascular Center is one of only three centers in the country to have this study available.

"If this study works, this procedure could prevent future patients from needing a heart transplantation or ventricular assist device, which is a mechanical circulatory device used to partially or completely replace the function of a failing heart," said Dr. Jerry Estep, cardiologist and medical director of the Methodist Heart Transplant program. "To be considered for this trial, individuals must have an existing need for [heart bypass surgery](#) and must have a left ventricular ejection fraction of 40 percent or less. Up to 42 subjects will be enrolled in this randomized study nationwide.

The research team cannot guarantee individual benefits from participating in the study.

The technology that processes the [stem cells](#), developed by Harvest Technologies, sorts the cells quickly, enabling the procedure to be intra-operative, rather than having the individual come in days prior to surgery for the [bone marrow](#) aspiration procedure.

Provided by Methodist Hospital System

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