

REVIVE-IT study to examine earlier device use for patients with heart failure

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The University of Michigan Cardiovascular Center and the University of Pittsburgh Medical Center will gain a new partner as it commences its study of earlier device use for patients with congestive heart failure.

Thoratec Corporation, maker of HeartMate II® left ventricular assist system, will provide up to \$11 million to co-sponsor the REVIVE-IT study with the National Institutes of Health's National Heart, Lung and Blood Institute, which is providing \$5.2 million of support.

REVIVE-IT will explore the potential benefits of left ventricular assist devices for the large and growing group of Americans with heart failure. Thoratec's HeartMate II® will be the study device.

University of Michigan and UPMC researchers will investigate whether patients with advanced heart failure who are not sick enough to meet current guidelines for an LVAD or a heart transplant do better with an LVAD than with current medical therapy.

[Principal investigators](#) include Keith Aaronson, M.D., M.S., medical director of the Heart Transplant Program and Center for Circulatory Support at the U-M Cardiovascular Center, Francis D. Pagani, M.D., Ph.D., surgical director of the Heart Transplant Program and the Center for Circulatory Support at the U-M and Robert Kormos, M.D., director of the UPMC Artificial Heart Program and co-director of the UPMC Heart Transplantation Program.

Douglas L. Mann, M.D., chief of the Cardiovascular Division at Washington University School of Medicine in St. Louis and cardiologist-in-chief at Barnes-Jewish Hospital, chairs the study's steering committee.

"We are excited to move forward with this important study to examine the use of LVADs earlier in the spectrum of heart failure," says Aaronson, professor of medicine at the U-M Medical School.

For most patients, either a past heart attack or certain conditions such as hypertension, heart muscle diseases, abnormal heart valves, or diabetes has led to heart failure.

LVADs are currently used in patients with very advanced heart failure as a last resort to help them survive the wait for a [heart transplant](#), or serve as a permanent alternative to heart transplantation.

"In REVIVE-IT we'll test the theory that patients with advanced heart failure whose condition impairs their daily lives, but who have not suffered serious consequences such as organ damage, malnourishment or immobility, would benefit from earlier implantation of an LVAD," says Pittsburgh's Kormos. Kormos is also co-principal investigator of the NHLBI-sponsored Interagency Registry for Mechanical Circulatory Support, which contains information on over 7,000 approved VADs.

U-M's Center for Circulatory Support is a multidisciplinary team of physicians, surgeons and allied health care providers dedicated to the care of patients with advanced heart failure or cardiogenic shock. Center clinicians and researchers have provided leadership in the clinical investigation of most of the implantable circulatory support devices in use today and to date have implanted more than 500 devices.

"Our work may advance the treatment of heart failure by evaluating whether technology now reserved for very severe heart failure is ready

for application to a broader group of patients in need," says Pagani, a cardiac surgeon and professor of cardiac surgery at the U-M Medical School.

The study will include 100 patients from hospitals across the United States. Patient enrollment is expected to begin later this year. The U-M's Michigan Institute for Clinical and Health Research will coordinate the study.

"Thoratec's mission is to advance the treatment of heart failure and the field of mechanical circulatory support. To that end, we are pleased to partner with preeminent VAD programs across the U.S., under the leadership of the U-M CVC and the UPMC, in the REVIVE-IT study," Thoratec President and Chief Executive Officer Gary F. Burbach said in a press release.

The HeartMate II is surgically placed just below the diaphragm and connected to the left ventricle and aorta to help pump blood from the heart to the entire body. Over 13,000 patients have been implanted with the HeartMate II, including 5,500 currently on circulatory support.

"VADs have been shown to improve both the quality and length of life in late-stage heart failure patients," says J. Timothy Baldwin, Ph.D., deputy branch chief of the Advanced Technologies and Surgery Branch, Division of Cardiovascular Sciences, NHLBI, and REVIVE-IT trial project officer. "This trial promises to help us learn if there are advantages to providing these devices earlier before [patients](#) reach late-stage [heart failure](#)."

Provided by University of Michigan Health System

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