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Study examines earlier use of heart pumps in growing group of heart failure patients

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The University of Michigan Cardiovascular Center and the University of Pittsburgh have been awarded $13.3 million to explore the potential benefits of heart devices for the large and growing group of Americans with heart failure.

The National Heart, Lung and Blood Institute and HeartWare International, a maker of left ventricular assist devices, are sponsoring the study of earlier access to these devices that support the circulation of patients with failing hearts.

In REVIVE-IT, researchers will compare whether non-transplant eligible patients with heart failure less advanced than that of current LVAD recipients do better with implanted devices 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 A. 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.

"The new study allows us to examine the use of heart devices earlier in the cascade of heart failure," says Aaronson, associate 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 lead 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 heart failure patients 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 nearly 2,000 approved assist devices.

"Ventricular assist devices have been shown to improve both the quality and length of life of late-stage heart failure patients," says J. Timothy Baldwin, Ph.D., REVIVE-IT trial project officer, Division of Cardiovascular Sciences, NHLBI. "This trial promises to help us learn if there are advantages to providing these devices before patients reach late-stage heart failure."

The REVIVE-IT study device will be HeartWare's left ventricular assist device the HVAD, a battery- operated continuous blood flow pump that's surgically placed within the heart and the pericardial space surrounding the heart.

The pilot study will include 100 patients from selected U.S. hospitals, including the U-M and Pittsburgh. Site selection for the study will begin later this year. The U-M's Michigan Institute for Clinical and Health

Research will coordinate the study.

"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 surgery at the U-M.

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.

"The University of Michigan and University of Pittsburgh have been leaders in exploration and development of new technologies for mechanical circulatory support," says Doug Godshall, president and chief executive officer of HeartWare International. "We look forward to supporting their efforts, as they direct this first-of-its-kind clinical study."

Provided by University of Michigan Health System